Exhibit 2

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VIA ELECTRONIC SUBMISSION
AND HAND DELIVERY

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

> **Re:** **Docket No. FDA-2019-N-3065 ("Tobacco Products; Required Warnings for Cigarette Packages and Advertisements")**

Dear Sir or Madam,

On August 16, 2019, the U.S. Food and Drug Administration ("FDA" or "the Agency") issued a proposed rule regarding graphic warnings for cigarette packaging and advertising. *See Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 84 Fed. Reg. 42,754 (Aug. 16, 2019). In response, RAI Services Company ("RAIS") respectfully submits these comments on its own behalf and on behalf of its affiliated tobacco companies.[1]

RAIS supports promoting public awareness of the harms of smoking cigarettes, including through appropriate warnings on tobacco products. RAIS is committed to working cooperatively with FDA to address this important public-health issue, and submits these comments in the spirit of advancing that shared goal.

Executive Summary

For decades, the government has used a multi-pronged approach to reducing smoking. First, the government has required that cigarette packages and advertising contain factual warnings about the health risks of smoking and other information. *See, e.g.*, Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965); Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2,200 (1984); Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1,776 (2009). Second, the government has systematically limited the

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[1] RAIS coordinates regulatory compliance for Reynolds American Inc.'s ("RAI") subsidiary companies, including R.J. Reynolds Tobacco Company; American Snuff Company, LLC; Santa Fe Natural Tobacco Company, Inc.; and R.J. Reynolds Vapor Company. References to RAIS or "the Company" in this letter may refer to RAIS itself and/or its affiliated RAI subsidiaries, as applicable.

avenues through which cigarette manufacturers can speak to adult smokers. For example, federal law prohibits cigarette companies from advertising through television or radio, and severely restricts them from selling or giving away branded merchandise, sponsoring events, and giving out free samples. 15 U.S.C. § 1335; 21 U.S.C. § 387a-1. Third, the government has run multiple public-health campaigns that informed the public about the health risks of smoking and urged smokers to quit. For example, the Surgeon General has published more than thirty reports on smoking and health, and between 2009 and 2014, FDA alone spent more than $500 million on anti-smoking campaigns. *See infra* pp. 13–14, 32.

This multi-pronged approach—requiring factual warning labels on every cigarette package and advertisement, advertising restrictions, and government advocacy—has been extremely successful at reinforcing and sustaining effectively universal public awareness of the dangers of smoking. In 1999, the Centers for Disease Control and Prevention ("CDC") recognized that the public widely understood the risks of smoking, and declared that understanding to be one of the ten greatest public health achievements of the twentieth century. CDC, *Ten Great Public Health Achievements—United States, 1900–1999* (Apr. 2, 1999), https://tinyurl.com/y8wfy53b.[2] Today, the public still universally understands those risks. For example, data from FDA's Population Assessment of Tobacco and Health ("PATH") survey shows that 99.5% of individuals believe that cigarette smoking is harmful to health, including 91% who believe that it is "very or extremely harmful," 7% who believe it is "somewhat harmful," and 1.5% who believe it is "slightly harmful." Klick Report ¶ 5.20; *see also infra* Section I.B.6(a).

Moreover, smoking prevalence and cigarette consumption are both down. Between 1965 and 2017, the percentage of adults who smoked cigarettes fell from 42.4% to 14%. Between 1981 and 2017, the number of cigarettes purchased annually in the United States dropped from 640 billion to 249 billion—a decline of more than 60% despite an increase in the U.S. population of more than 100 million. And between 1997 and 2018, the percentage of high school students who smoked fell from 36.4% to 8.1%. *See* 84 Fed. Reg. at 42,758 ("[C]igarette smoking prevalence has generally declined over the past several decades[.]"). Indeed, youth and adult smoking rates are at historic lows. *See infra* p. 23.

Despite this success, however, a small percentage of Americans choose to continue smoking. Frustrated by that reality, FDA has decided to change tacks: instead of informing the public about smoking risks as it has done to date, the Agency plans to force cigarette *manufacturers* to convert their packaging into a government-controlled, anti-smoking communication tool. And instead of using factual warnings, the Agency plans to force manufacturers to use gruesome and exaggerated images—essentially compelling manufacturers to disparage their own products, and frighten and shame their own customers.

The first time FDA issued a graphic-warnings rule, the Agency was clear about its motives. FDA admitted that the point of graphic warnings was to "rebrand[] our cigarette packs"; convey that "smoking is gross"; "dispel[] the notion that somehow [smoking] is cool"; and "encourage smokers to quit." Press Briefing by Press Secretary Jay Carney, Secretary of Health and Human Services Kathleen Sebelius, and FDA Commissioner Margaret Hamburg (June 21, 2011),

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[2] All web addresses in these comments have been shortened using TinyURL, which results in a web address that contains "tinyurl.com."

https://tinyurl.com/yyxc8x88. Indeed, FDA admitted that graphic warnings were designed to make "'every single pack of cigarettes in the country a mini billboard' for the government's anti-smoking message." *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1212 (D.C. Cir. 2012) (quoting FDA, *Tobacco Strategy Announcement* (Nov. 10, 2010)). This time around FDA has decided to be less transparent, saying that it merely wants to "promote greater public understanding of the negative health consequences of cigarette smoking." 84 Fed. Reg. at 42,755. But this "contrived" rationale cannot disguise the Agency's real goal. *See Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2575–76 (2019).

The proposed rule would mandate that manufacturers use the top 50% of the front and back of cigarette packages, and at least the top 20% of cigarette advertisements, to present the government's anti-smoking messages. And the proposed rule does *not* restrict itself to requiring the disclosure of factual information that would enable smokers to make better-informed decisions. To the contrary, the warnings use gruesome, inflammatory images that are plainly designed to evoke negative emotions, such as fear, disgust, and distress. In short, the warnings are supposed to trumpet the government's preferred ideological message: don't smoke. *See infra* Section I.B.1.

The First Amendment flatly forbids FDA's attempt to commandeer manufacturers' speech in order to remove a "popular but disfavored product from the marketplace." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 577–78 (2011). Specifically, the Tobacco Control Act's graphic-warnings requirement and the proposed rule violate the First Amendment in the following ways:

First, FDA has not identified a legally sufficient governmental interest to justify this extreme rule. FDA says that it wants to "promote greater public understanding of the negative health consequences of cigarette smoking." 84 Fed. Reg. at 42,755. But this information is not necessary to prevent consumer deception, and it will not have any real-world effect on how consumers behave. In other words, FDA wants to give people information for information's sake. As the D.C. Circuit has already held, however, "FDA's interest in 'effectively communicating' the health risks of smoking is merely a description of the means by which it plans to accomplish its goal of reducing smoking rates, and not an independent interest capable of sustaining [a graphic-warnings rule]." *R.J. Reynolds*, 696 F.3d at 1221; *see also infra* Section I.B.4–5.

Second, even if FDA's asserted interest were valid, the proposed rule would not advance it. FDA says that it wants to increase public understanding by correcting various "misperceptions" that the public supposedly has about smoking. But that is a purely hypothetical problem. Multiple data sources demonstrate that the public already knows that smoking is harmful and can cause serious diseases. Indeed, this fact is illustrated by FDA's decision *against* using several of the warnings prescribed by Congress in the Tobacco Control Act, such as "Smoking can kill you," because they do not tell the public anything that it does not already know. *See infra* pp. 14–15.

FDA tries to sidestep this problem by adopting warnings that supposedly focus on "less-known health consequences of smoking." 84 Fed. Reg at 42,755. Yet the proposed rule fails to demonstrate that the public does not understand these risks. Once again, PATH data and other surveys show widespread public awareness of many of the risks that FDA describes as "less-known." And FDA does shockingly little to contradict those surveys—indeed, virtually every study that FDA cites is outdated, focuses on foreign countries, or focuses on a smoking risk that FDA decided not to address in the proposed rule. Most importantly, in the proposed rule, FDA

effectively concedes that the public knows many of the risks identified in the proposed warnings, such as the risks of secondhand smoke, lung disease, strokes, and heart disease. *See infra* pp. 15–18.

Moreover, even if the public lacked sufficient understanding of some less-known risks, FDA cannot show that graphic warnings would remedy that problem. As explained above, graphic warnings evoke negative emotions such as fear, shame, and disgust. But the "empirical evidence on the use of emotional appeals in warnings is mixed at best." Klick Report ¶ 5.81. FDA's second consumer research study confirms the point. In that study, FDA tested participants' health beliefs ("Session 1"), showed them the proposed warnings, and then tested their health beliefs one day later ("Session 2") and fourteen days later ("Session 3"). At the end of that process, five of the warnings had actually *reduced* the participants' knowledge about the relevant health risks, and seven of the remaining eight warnings saw sharp decreases in knowledge gains between Session 2 and Session 3. *See infra* pp. 18–20.

Even worse, FDA cannot show that the warnings would meaningfully change how people think about the overall risk of smoking or whether they smoke. Dr. Jonathan Klick, a leading expert on the causal effects of health regulations on behavior, analyzed PATH data to determine whether smokers find the risks identified in the proposed warnings to be material. The answer was a resounding no. Klick Report ¶ 5.29–40. Indeed, Dr. Klick's analysis shows that awareness of the particular risks that relate to the FDA's proposed warnings has no effect on smoking behavior and generally has no effect on overall risk assessment. *Id.* ¶ 5.37. This result is devastating to the proposed rule's "information for information's sake" rationale; FDA therefore chose *not* to rely on this PATH data, even though the PATH survey was "started explicitly to inform the FDA's regulatory decisions and actions with respect to smoking." *Id.* ¶ 5.18; *see also infra* pp. 20–22.

Finally, FDA cannot show that the proposed warnings would reduce smoking. In the first graphic-warnings rule, FDA argued that the warnings would "decrease smoking initiation and increase smoking cessation." *Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36,628, 36,719 (June 22, 2011). But FDA failed to produce even a "shred of evidence" that the warnings would have that effect. *R.J. Reynolds*, 696 F.3d at 1219. Indeed, FDA's own study determined that the warnings would reduce smoking rates by a mere 0.088%, a number that FDA conceded was "not statistically distinguishable from zero." 76 Fed. Reg. at 36,775–76. Nothing has changed in the past eight years, and FDA has not even *tried* to demonstrate otherwise.

Third, the Tobacco Control Act's graphic-warnings requirement and the proposed rule are insufficiently tailored. The warnings would dominate cigarette packaging: occupying 50% of the front and back panels with identical FDA messages, and using frightening images that are designed to pull people's attention away from the rest of the pack. The combined effect of these requirements would harm cigarette manufacturers' ability to communicate with their consumers. The proposed rule would seize a huge portion of every cigarette package to convey the government's own anti-smoking message. That message would occupy the most prominent part of the package—and often the only part of the package that consumers could see. Thus, when adult cigarette consumers look at a pack of cigarettes, they will see only one thing: the government's anti-smoking message. Those are huge burdens, and they render cigarette packaging—one of the last remaining mediums for cigarette manufacturers to communicate with their consumers—much less effective. *See infra* pp. 25–31.

Moreover, FDA has many less-restrictive alternatives to achieve its goals. For example, FDA could have achieved its goals of bringing attention to "less-known health consequences of smoking" simply by changing the text of the Surgeon General's warnings. Or FDA could have run a public-education campaign about the risks of smoking—an option that the Agency has repeatedly promoted as "highly successful" and "yielding tremendous results." Norman E. Sharpless, *Press Announcement* (Aug. 20, 2019), https://tinyurl.com/y3kmouoa. Indeed, the same week that FDA issued the proposed rule, FDA touted a study asserting that its *Real Cost* youth anti-smoking campaign has "prevented up to 587,000 youth nationwide from initiating smoking between the campaign's launch in February 2014 and November 2016, half of whom might have gone on to become established smokers." *Id.* FDA has demonstrated its ability to deliver public-health messages, including regarding tobacco health risks, and thus had every reason to try to do so here as well. *See infra* pp. 31–34.

In addition to violating the First Amendment, the proposed rule has other fatal flaws. The proposed rule violates the Tobacco Control Act by changing the language of the textual warnings, as well as the total number of warnings, without authority. *See infra* Section II. The proposed rule also violates the Administrative Procedure Act in multiple ways. *See infra* Section III. For example, FDA relied on an inadequate cost-benefit analysis, which failed to quantify the benefits of the proposed rule. The Agency recognized that "there is a high level of uncertainty around quantitative economic benefits"—a fancy way of saying that the proposed rule might not have any benefits at all. Faced with that possibility, FDA did not even *try* to calculate the benefits. *See infra* Section III.A.

As another example, FDA has not given the public a meaningful, legally sufficient chance to comment on the proposed rule. FDA has been working on the proposed rule for years. During that time, FDA had plenty of opportunities to tell the public what it was doing or share its ongoing research—indeed, RAIS's outside counsel tried to get the Agency to do precisely that in June 2017 by submitting a Freedom of Information Act (FOIA) request. But FDA has obfuscated every step of the way: refusing to respond to the FOIA request, refusing to release the results of its consumer research studies, and even asking the public to comment on its final graphic-warnings study *without telling the public which graphic warnings it was testing*. That obfuscation has continued with the proposed rule: FDA again refused to release any information about its qualitative studies and has not released the underlying data from its quantitative studies, all of which were critical to the development of the proposed warnings. To top it all off, FDA has given the public a mere 60 days to come up with alternative graphic warnings—a process that took the Agency more than six years to complete—which would, of course, be impossible. *See infra* Section III.D.

FDA's approach up to this point demonstrates that the Agency has no interest in working collaboratively with the public on this issue. FDA has failed to keep the public informed. And FDA has given the public insufficient time to come up with alternative graphic warnings, perhaps because the Agency does not plan to consider those alternatives. This is the same dismissive approach that FDA took when developing the first graphic-warnings rule, an approach that led directly to that rule's downfall. *See R.J. Reynolds*, 696 F.3d at 1210, 1219–20.

The Tobacco Control Act's graphic-warnings requirement violates the First Amendment, and FDA has exacerbated the problem by issuing a proposed rule that violates the First Amendment, the Tobacco Control Act, and the Administrative Procedure Act. FDA has only one

option: withdraw the proposed rule and refuse to enforce the unconstitutional graphic-warnings requirement.

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COMMENTS

I. THE TOBACCO CONTROL ACT'S GRAPHIC-WARNINGS REQUIREMENT AND THE PROPOSED RULE VIOLATE THE FIRST AMENDMENT.

FDA's proposed rule, and the provision of the Tobacco Control Act that requires it, suffer from a fundamental problem: they violate the First Amendment. Neither can survive strict scrutiny because they are not narrowly tailored and because the government lacks a compelling interest. They also cannot survive the *Zauderer* standard for a host of reasons: the warnings are not "purely factual" because they are intended to evoke an emotional response and convey an ideological, anti-smoking message; the warnings are "controversial" because they are misleading and inflammatory; the warnings are "unjustified" because they do not remedy a real-world harm; the warnings are "unduly burdensome" because they commandeer 50% of cigarette packaging and at least 20% of cigarette advertisements for gruesome images; and the government does not have a substantial interest in telling people things they already know or giving people information for information's sake. The Act's graphic-warnings requirement and the proposed rule cannot survive the *Central Hudson* standard for similar reasons.

A. The graphic-warnings requirement and the proposed rule are subject to strict scrutiny, a standard they cannot possibly meet.

1. "Since *all* speech inherently involves choices of what to say and what to leave unsaid, one important manifestation of the principle of free speech is that one who chooses to speak may also decide what not to say." *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Boston*, 515 U.S. 557, 573 (1995) (citations and quotation marks omitted). Thus, the "general rule" is that the government "may not compel affirmance of a belief with which the speaker disagrees." *Id.* This rule "applies not only to expressions of value, opinion, or endorsement, but equally to statements of fact the speaker would rather avoid." *Id.* And it applies to "ordinary people" and "business corporations" alike. *Id.* at 574. "For corporations as for individuals, the choice to speak includes within it the choice of what not to say." *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1, 16 (1986) (plurality op.).

In light of these principles, courts generally apply strict scrutiny to government-compelled speech. *See, e.g.*, *Wooley v. Maynard*, 430 U.S. 705, 714–15 (1977); *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2226–27 (2015). Under strict scrutiny, the government must prove that the compulsion "furthers a compelling interest and is narrowly tailored to achieve that interest." *Reed*, 135 S. Ct. at 2231.

Here, the Tobacco Control Act's graphic-warnings requirement and the proposed rule would compel manufacturers to express the government's preferred anti-smoking message. *See R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1211 (D.C. Cir. 2012) (holding that FDA's initial graphic-warnings rule "contain[ed] elements of compulsion and forced subsidization" and was therefore subject to First Amendment scrutiny), *overruled in part by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 31 (D.C. Cir. 2014) (en banc). The graphic-warnings requirement and the proposed rule are therefore subject to strict scrutiny.

2. The graphic-warnings requirement and the proposed rule do not even begin to meet strict scrutiny for two reasons. First, the government lacks a compelling interest in requiring graphic warnings. FDA asserts only a single interest: "promoting greater public understanding of the negative health consequences of cigarette smoking." 84 Fed. Reg. at 42,755. But FDA describes this interest as "substantial," rather than "compelling." *See id.* at 42,778. And as explained below, FDA does not have even a substantial interest in "promoting greater public understanding." *See infra* Section I.B.5.

Second, the graphic-warnings requirement and the proposed rule are not narrowly tailored to achieve the government's interest. Before compelling speech, the government has the burden to prove that plausible less-restrictive alternatives are not sufficiently effective. *See Ashcroft v. ACLU*, 542 U.S. 656, 665 (2004) ("When plaintiffs challenge a content-based speech restriction, *the burden is on the Government* to prove that the proposed alternatives will not be as effective as the challenged statute." (emphasis added)). Here, Congress could have adopted numerous less-restrictive alternatives that would have been at least as effective as graphic warnings.

Most obviously, Congress could have made less-restrictive changes to the existing cigarette warnings. The Tobacco Control Act changed the existing warnings in several ways: it created nine new textual warnings, 15 U.S.C. § 1333(a)(1); it required that the warnings appear "in the upper portion of the front and rear panels of the package," *id.* § 1333(a)(2); it required that the label "comprise the top 50 percent of the front and rear panels of the package," *id.*; and it required that FDA create "color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1)," *id.* § 1333(d). Congress could have selected one or more of these possible changes to fashion a less-restrictive alternative to a graphic-warnings rule. For example, Congress could have required that manufacturers replace the existing Surgeon General's warnings with the Act's new textual warnings. Or Congress could have required that manufacturers use the new textual warnings and place them at the top of the package. Or Congress could have required that manufacturers use graphic images that were smaller or depicted something other than the negative health consequences of smoking. Any of these examples would have been less-restrictive and equally effective at conveying factual information. *See infra* pp. 31–32.

Congress also could have required FDA to run a public-education campaign about the health risks of smoking, and appropriated sufficient funds for that campaign. As marketing expert Professor Joannes Evangelista Steenkamp explains, "the FDA has at its disposal a number of social marketing tools that would allow the FDA to achieve its informational objectives without needing to mandate graphic health warnings." Steenkamp Report at 2 (attached as Exhibit D). This approach actually would have been *more* effective at promoting public understanding of the health risks of smoking: such a campaign could have "target[ed] different specific segments [of the population] using dynamic, real-time executional elements" rather than relying on "static" graphic warnings. *Id.*; *see also infra* pp. 32–33.

FDA likewise could have adopted one of these less-restrictive alternatives. To be sure, the Tobacco Control Act purports to require FDA to adopt graphic warnings. But FDA has a constitutional responsibility to comply with the First Amendment, and the Agency cannot evade that responsibility simply because a statute says to do so. *See, e.g., Boumediene v. Bush*, 553 U.S. 723, 798 (2008) (noting that the political branches have "independent obligations to interpret and

uphold the Constitution"); *Trump v. Hawaii*, 138 S. Ct. 2392, 2424 (2018) (Kennedy, J., concurring) (stating that all government officials must "adhere to the Constitution"); Walter Dellinger, *The Constitutional Separation of Powers Between the President and Congress*, 20 U.S. Op. Off. Legal Counsel 124, 128 (1996) (observing that "the executive branch has an independent constitutional obligation to interpret and apply the Constitution"). Indeed, the Oaths Clause of the Constitution provides that all executive officers are "bound by Oath or Affirmation, to support this Constitution." U.S. Const., Art. VI cl. 3; *see also Ableman v. Booth,* 62 U.S. 506, 524 (1858) (suggesting that the inclusion of the Oaths Clause reflects the Framers' intention to preserve the "full force" of the Constitution"); *Gamble v. United States*, 139 S. Ct. 1960, 1985 (2019) (Thomas, J., concurring) (suggesting that the Oaths Clause reflects "[t]he Constitution's supremacy"). And even if FDA felt compelled to adopt graphic warnings, the Agency still could have adopted less-restrictive warnings—for example, by using images that were less provocative.

Notably, FDA implicitly concedes that the graphic-warnings requirement and the proposed rule cannot satisfy strict scrutiny. In the proposed rule, FDA says that "the warnings would pass a First Amendment analysis under *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985) (or, if applied, *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980))." 84 Fed. Reg. at 42,757. But FDA does *not* say that the warnings would pass a First Amendment analysis under strict scrutiny. Because strict scrutiny is the correct standard, the graphic-warnings requirement and the proposed rule are unconstitutional.

B. The *Zauderer* standard of review does not save the graphic-warnings requirement or the proposed rule.

FDA suggests that the proposed rule "would pass a First Amendment analysis under *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985)." 84 Fed. Reg. at 42,757. Under *Zauderer*, the government may require manufacturers to disclose "purely factual and uncontroversial information about the terms under which [their] services will be available," so long as those disclosures are "reasonably related to the State's interest in preventing deception of consumers" and are not "unjustified or unduly burdensome." *Zauderer*, 471 U.S. at 651. But the graphic-warnings requirement and the proposed rule fail every part of the *Zauderer* test.

1. Graphic warnings are not "purely factual" because they are intended to evoke an emotional response and convey an ideological, anti-smoking message.

Under *Zauderer*, a compelled disclosure must be "purely factual." *Id.* A compelled disclosure fails that standard if the disclosure is "primarily intended to evoke an emotional response," to "shock the viewer into retaining the information," or to convey an ideological message about how consumers should behave. *R.J. Reynolds*, 696 F.3d at 1216–17. For example, the D.C. Circuit held that FDA's first graphic warnings were not purely factual because they were "unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting." *Id.*; *see also Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006) (holding that a compelled disclosure failed *Zauderer* because it was "opinion-based" and "subjective" rather than "purely factual").

a. On its face, the Tobacco Control Act's graphic-warnings requirement fails the "purely factual" test. The Act requires FDA to adopt "color graphics depicting the negative health consequences of smoking." 15 U.S.C. § 1333(d). And the point of that requirement is to evoke negative emotions, shock the viewer, and convey the government's anti-smoking message. As Senator Mike Enzi explained:

> We should want kids who are thinking about taking up this deadly habit to have a bit of a shock just by looking at the package. We should want smokers to think about these health issues each time they light up. Any tool in our arsenal that makes people think twice about taking up tobacco should not be an option, it should be a requirement.

155 Cong. Rec. S6497, S6499 (2009).

FDA has acknowledged this commonsense point. The first time that FDA proposed graphic warnings, the Agency picked a number of gruesome images, such as diseased lungs, a cancerous lesion on a person's lip, and a man smoking through a hole in his throat. FDA freely admitted that these images were designed to "rebrand[] our cigarette packs"; convey that "smoking is gross"; "dispel[] the notion that somehow [smoking] is cool"; and "encourage smokers to quit." Press Briefing by Press Secretary Jay Carney, Secretary of Health and Human Services Kathleen Sebelius, and FDA Commissioner Margaret Hamburg (June 21, 2011), https://tinyurl.com/yyxc8x88. Indeed, FDA admitted that graphic warnings were designed to make "'every single pack of cigarettes in the country [a] mini billboard' for the government's anti-smoking message." *R.J. Reynolds*, 696 F.3d at 1212 (quoting FDA, *Tobacco Strategy Announcement* (Nov. 10, 2010)). In light of these admissions, and the horrific nature of the images themselves, the D.C. Circuit held that the warnings were transparently designed "to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting." *R.J. Reynolds*, 696 F.3d at 1216–17. Thus, the court had no trouble concluding that the warnings were not "purely factual." *R.J. Reynolds*, 696 F.3d at 1217.

The scientific literature confirms that graphic warnings are not purely factual. As multiple public-health researchers have acknowledged, forcing consumers to look at such gruesome images evokes feelings of fear, shame, and disgust, and conveys the ideological message that people should not smoke. *See, e.g.*, Andrews et al. 2016, at e122–23 (finding that graphic warnings evoked feelings of fear and embarrassment); Hardcastle et al. 2016, at 98 (finding that "plain packaging"— which included bigger and more prominent graphic warnings—resulted in "increased negative emotional reactions including feelings of threat, blame, and shame"); *see also* Byrne et al. 2015, at 683; Cameron et al. 2015, at e21; Drovandi et al. 2019, at 4–7; Evans et al. 2015, at 2; Glock et al. 2013, at 252–53; Hammond 2009, at 23; Hammond 2011, at 331–32.[3]

Indeed, the *whole point* of graphic warnings is to evoke those feelings and convey that ideological message. A leading researcher candidly admitted as much in a grant application that RAIS obtained through a Freedom of Information Act request. This researcher applied for a grant from the National Institutes of Health to conduct graphic-warnings research. *See* James Thrasher,

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[3] For sources cited only in short citation form, the full citations appear in Exhibit A. In addition, the publicly available studies and articles listed in Exhibit A are being filed as Exhibit B to the RAIS comments. (Exhibit B is being filed in hard copy; all other exhibits are being filed electronically and in hard copy.)

Annual Report to the National Institutes of Health Regarding Grant Funding (Mar. 16, 2016) (attached as Exhibit O). He acknowledged that graphic warnings triggered a sharp emotional response, and described that response as an "indicator[] of greater message engagement and greater effectiveness." *Id.* at 7. The researcher explained that this point was "important because the legal case against implementation of graphic warnings in the [United States] was partly argued on the basis of their emotional appeal, as though it is possible to strip away affect and effectively communicate information." *Id.* He concluded, however, that "[t]hese and other studies we are conducting suggest otherwise." *Id.* In other words, this researcher frankly admitted that it is *impossible* to "strip away" emotion from graphic warnings and still "effectively communicate information."

b. FDA's proposed warnings likewise fail the "purely factual" test. To take just a few examples, the proposed warnings include a picture of diseased feet with several amputated toes, a picture of a woman with a massive cancerous lump on her neck, and two pictures of blackened, diseased lungs. As a litany of news outlets have recognized, these graphic warnings are plainly designed to scare, shame, and disgust people, and to convey an ideological, anti-smoking message, just like their predecessors. For example:

- The Washington Post called the warnings "scary" and "unsettling," and noted that the D.C. Circuit previously struck down "similarly graphic labels." Lindsey Bever, *FDA's Proposed New Cigarette Warnings Are Scary. That's the Point*, Washington Post (Aug. 15, 2019), https://tinyurl.com/y4zuqssj.

- The New York Times called the warnings "disturbing." Sheila Kaplan, *The F.D.A.'s New Cigarette Warnings Are Disturbing. See for Yourself.*, N.Y. Times (Aug. 15, 2019), https://tinyurl.com/y366q2l5.

- Psychiatry Advisor called the warnings "gruesome." Psychiatry Advisor, *FDA Proposed Graphic Warning Labels on Cigarettes* (Aug. 26, 2019), https://tinyurl.com/yyvket6w.

- The Huffington Post called the warnings "ghastly" and "grisly reminders of what could happen to [smokers'] bodies," and described the proposed rule as FDA's "latest plan to deter smokers from lighting up." Amy Russo, *FDA Unveils New Round Of Ghastly Cigarette Warnings In Anti-Smoking Push*, HuffPost (Aug. 16, 2019), https://tinyurl.com/y34tm2sd.

The public has gotten the message. Indeed, when asked what message the proposed warnings send, several respondents said the following:

- "The government is using scare tactics to obtain control over the population."

- "trying to scare people"

- "im grossed out"

Iyengar Report ¶ 22 (attached as Exhibit E).

In addition to these common-sense reactions, both qualitative and quantitative evidence demonstrate that the proposed warnings are no better than the last set. Dr. Jonathan Klick, a leading expert on the causal effects of health regulations on behavior, explains that the images themselves make it "evident that the FDA is appealing to fear and disgust." Klick Report ¶ 5.80 (attached as Exhibit C). Dr. John Martin, a behavioral-health psychologist with years of experience helping smokers quit, likewise explains that the proposed warnings are designed "to increase fear in smokers." Martin Report at 7 (attached as Exhibit F).

Moreover, FDA's consumer research studies confirm that the proposed warnings are not "purely factual." FDA's first consumer research study showed that *seven* of the proposed warning statements were *less* believable than the Tobacco Control Act's warning statements, and only *one* proposed warning statement was *more* believable. Study 1 Results Report at 3-9. And FDA's second consumer research study showed that *eight* of the proposed warnings were *less* likely to be perceived as factual than the Surgeon General's warnings. *See* Study 2 Results Report § 3.2.3; *see also* Klick Report ¶¶ 8.2–8.3.

A recent survey of smokers and non-smokers likewise demonstrates that the proposed warnings are not "purely factual." For example, after viewing five proposed warnings selected at random, 85.9% of respondents said that the warnings were "trying to make people feel afraid." Iyengar Report ¶ 29 & Appendix 3. Approximately the same percentage said that the warnings were "trying to shock people." *Id.* In addition, 74.5% of respondents said that the warnings conveyed the message that people should not smoke cigarettes, and 68.2% of respondents said that the warnings conveyed the message that people should not buy cigarettes. *Id.* at ¶ 31 & Appendix 3.

c. In *R.J. Reynolds*, the D.C. Circuit held that FDA's first graphic warnings flunked the *Zauderer* test because they were designed "to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting." 696 F.3d at 1216–17. Thus, the court had no trouble concluding that the warnings were not "purely factual." *R.J. Reynolds*, 696 F.3d at 1217. In the proposed rule, FDA says that it "carefully considered" that holding and went through a "science-based, iterative research process" to "thoroughly address[] any such criticisms." 84 Fed. Reg. at 42,777–78. But FDA did no such thing. On the contrary, the proposed rule demonstrates that FDA did *nothing* to determine whether the proposed warnings evoke emotion or convey an anti-smoking message. FDA has published all three survey instruments that the Agency used to test the proposed warnings, and those surveys do not include a *single* question about whether the warnings evoke emotion or convey the message that people should not smoke. As Dr. Klick explains, "FDA did not test, report testing, and/or provide any qualitative research disclosing that it had tried to prevent emotional responses to the proposed warnings or that it tried to mitigate any such effect." Klick Report ¶ 5.80. Accordingly, the Agency has not gone through a "science-based, iterative research process" on this important issue. 84 Fed. Reg. at 42,755.

2. Graphic warnings are not "uncontroversial" because they are misleading and use inflammatory images.

a. *Zauderer* also requires that compelled disclosures be "uncontroversial." 471 U.S. at 651. A disclosure is "controversial" if it is potentially inaccurate or misleading. *See Entm't Software*, 469 F.3d at 652 (holding that a disclosure was "controversial" because the speaker might reasonably disagree with the message); *R.J. Reynolds*, 696 F.3d at 1216 (holding that FDA's graphic warnings did not fall within *Zauderer* because, among other reasons, "many of the images chosen by FDA could be misinterpreted by consumers").

Here, the proposed warnings are inaccurate or misleading in a number of respects. Several of the images exaggerate the effects of the diseases they purport to represent, exaggerate the likelihood of those diseases being caused by smoking, or offer a misleading portrayal of the treatment of those diseases. In particular:

- The warning pertaining to macular degeneration misrepresents the treatment for that condition. It depicts a far thicker needle than is used in reality, and it depicts the needle being inserted in the center of the eye, rather than in the lower outer area of the eye (where it is typically inserted in reality). *See* Dr. Davidorf Declaration at 2 (attached as Exhibit H). As a result, the warning "may give rise to the false impression that the treatment is painful," when in reality it is not. *Id.* This has the pernicious potential to "frighten[] patients away from beneficial treatment." *Id.*; *see also* Am. Optometric Assoc. Comments, Docket No. FDA-2019-N-3065, at 3 (Oct. 15, 2019) (explaining that this warning will "create fear and distance between patients and necessary medical interventions and/or treatments").

- The warning pertaining to cataracts is "not a reasonable depiction of persons with cataracts in the US, because in the US the cataract would have been treated surgically long before it got to this stage." Dr. Davidorf Declaration at 3. In addition, the image misleadingly "makes the cataract look like a cosmetic problem," when in reality "[t]he vast majority of patients who undergo cataract surgery in the US have cataracts that are undetectable by the unaided human eye." *Id.*

- The warning pertaining to head and neck cancer is likewise "unlikely [to] be accurately understood" by the public. Dr. Jones Declaration ¶ 4 (attached as Exhibit J). The image is misleading to the extent it suggests that "a cancerous mass of that size could arise quickly enough that a reasonable person would not have had an opportunity to seek treatment before this point." *Id.* ¶ 5.

- The warning pertaining to lung disease in nonsmokers suffers from "two major flaws." Dr. Farber Declaration ¶ 4 (attached as Exhibit I). First, "the lungs do not look like a non-smoker's lungs." *Id.* In particular, the image depicts an "amount of black pigmentation" that "would likely result from many years of heavy direct smoking" and would be "very unusual … in a non-smoker." *Id.* ¶ 5. Second, its depiction of lesions is both "ambiguous" and "inaccurate." The warning is unclear whether the lesions were meant to depict lung cancer. If so,

the image is misleading because the lesions appear on the surface of the lung (rather than deep within the lung), and because it would be "unusual" for a non-smoker to have three separate lesions of the size depicted. *Id.* ¶¶ 5, 6.

- The warning pertaining to blood flow to the limbs is misleading because it depicts a condition that could affect, at most, one in 1,000 smokers. Dr. Wagmeister Declaration ¶ 4 (attached as Exhibit K).

- The warning pertaining to fetal growth is misleading because it shows a newborn infant weighing four pounds. But according to the U.S. Surgeon General, the low range of normal birth weight is 2,500 grams, and infants born to women who smoke cigarettes weigh approximately 200 grams less than infants born to non-smoking women. CDC, *The Health Consequences of Smoking: A Report of the Surgeon General* 555 (2004), https://tinyurl.com/y4gb8e4c; CDC, *How Tobacco Smoke Causes Disease: the Biology and Behavioral Basis for Smoking Attributable Disease: A Report of the Surgeon General* 538 (2010), https://tinyurl.com/y5wewxku. Thus, conservatively assuming that a normal birth weight of 2,500 grams (the low end of normal birth weight for infants) is decreased by 200 grams due to cigarette smoking, the resulting birthweight is 2,300 grams, or more than five pounds.

- The warning pertaining to heart disease and strokes depicts a man who has had recent open heart surgery, presumably coronary artery bypass grafting (CABG). But recent data reveal that open-heart CABG surgery is not the most common procedure for treating coronary artery disease. Instead, in-patient percutaneous coronary interventions (PCIs), are 2.5 times more common. American Heart Association, *Heart Disease and Stroke Statistics, 2019 Update* e513 (2019), https://tinyurl.com/y8rcqwdb. And this does not account for the significant number of PCIs that are performed on an out-patient basis. *Id.* at e511. Moreover, the use of CABG has been declining over time. *Id.*

- The warning pertaining to harm to children appears to depict a "worst case scenario": "a child hospitalized due to an asthma attack caused by environmental tobacco smoke." Dr. Brooks Declaration ¶ 4 (attached as Exhibit G). To the extent the warning is intended to depict an oxygen mask, it is "exaggerating" because it is "uncommon for a child with an asthma attack to require oxygen." *Id.* ¶ 5. Moreover, only about eight percent of children have asthma, and only five to six percent of children with asthma are hospitalized each year (and of course there are many potential causes of such hospitalizations besides environmental tobacco smoke, such as air pollution and allergens). *Id.* ¶¶ 7–8.

FDA acknowledges that the warnings should not address "rare" diseases, and that the images should depict "disease states and symptoms as they are typically experienced." 84 Fed. Reg. at 42,767, 42,770. As the medical evidence discussed above demonstrates, however, FDA has ignored its own advice.

b. In *R.J. Reynolds*, the D.C. Circuit held that FDA's first graphic warnings failed the *Zauderer* test because they "could be misinterpreted by consumers." 696 F.3d at 1216. In the

proposed rule, FDA again says that it "carefully considered" the court's holding and went through a "science-based, iterative research process" to "thoroughly address[] any such criticisms." 84 Fed. Reg. at 42,777–78. But the proposed rule again belies FDA's assertion.

FDA first tries to rely on a series of focus groups, in which consumers allegedly "provided qualitative feedback on [their] comprehension of each potential statement." 84 Fed. Reg. at 42,778. But FDA has not provided *any* information about those focus groups, so FDA cannot rely on them here. FDA next points to the two consumer research studies that it performed. *Id.* But neither study tested whether the proposed warnings are misleading. Those studies tested whether the warnings conveyed "new information" or whether consumers "learned something" from the warnings, but FDA did *not* ask respondents *what* information the warnings conveyed or *what* the respondents learned. Thus, the studies cannot rebut the evidence above that the proposed warnings are misleading.

c. A compelled disclosure is also "controversial" if it is inflammatory. *See Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2372 (2018) ("*NIFLA*") (noting that a compelled disclosure involved abortion—which was "anything but an 'uncontroversial' topic"— and that *Zauderer* therefore did not apply); *Cigar Ass'n of Am. v. FDA*, 315 F. Supp. 3d 143, 165–66 (D.D.C. 2018) (explaining that an "inflammatory" disclosure would be "controversial" under *Zauderer*). That means that graphic warnings are *necessarily* inflammatory. As explained above, the Tobacco Control Act requires FDA to adopt images that "depict[] the negative health consequences of smoking." 15 U.S.C. § 1333(d). Such images will *always* evoke negative emotions like fear, shame, and disgust, which means that those images will *always* be inflammatory. Thus, *Zauderer* does not apply to the graphic-warnings requirement or the proposed rule.

3. Graphic warnings do not disclose information about "the terms under which services will be available."

In *Zauderer*, the Supreme Court upheld a compelled disclosure because it involved "purely factual and uncontroversial information *about the terms under which [an attorney's] services will be available.*" 471 U.S. at 651 (emphasis added). The Court recently confirmed that this is an essential limit on *Zauderer*. *See NIFLA*, 138 S. Ct. at 2372. In *NIFLA*, the Court explained that *Zauderer* did not apply because the compelled disclosure at issue was "not limited to purely factual and uncontroversial information about the terms under which services will be available." *Id.* (ellipsis and quotation marks omitted). Indeed, the Court explained that the disclosure "in no way relates to the services that [the speakers] provide," and "[a]ccordingly, *Zauderer* has no application here." *Id.*; *see also id.* (citing *Hurley*, 515 U.S. at 573, for the proposition that "*Zauderer* does not apply outside of these circumstances").

Likewise, a Ninth Circuit judge recently recognized that *Zauderer* is limited to disclosures about "the terms on which … advertisers provide their services." *Am. Beverage Ass'n v. City & Cty. of San Francisco*, 916 F.3d 749, 761 (9th Cir. 2019) (Ikuta, J., concurring). Because of that limitation, Judge Ikuta concluded that *Zauderer* did not apply to a compelled disclosure about "sugar-sweetened beverages, which is a product rather than a service." *Id.*

Applying that logic here, *Zauderer* does not apply to the graphic-warnings requirement or the proposed rule. The graphic-warnings requirement does not involve a disclosure "about the terms under which *services* will be available." *Zauderer*, 471 U.S. at 651 (emphasis added). Instead, it applies to cigarettes, which are "a product rather than a service." *Am. Beverage*, 916 F.3d at 761. *Zauderer* is therefore inapplicable.

4. Graphic warnings are not "reasonably related to the government's interest in preventing deception of consumers."

The Tobacco Control Act's graphic-warnings requirement and the proposed rule fail to satisfy *Zauderer* for another reason: they are not reasonably related to preventing consumer deception. In *Zauderer*, the Supreme Court said that compelled disclosures are subject to lower scrutiny only if they are "reasonably related" to a specific interest: "preventing deception of consumers." 471 U.S. at 651. In later opinions, the Supreme Court confirmed that view of *Zauderer*. *See Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 250 (2010) (applying *Zauderer* because, as "in that case, [the] required disclosures are intended to combat the problem of inherently misleading commercial advertisements"); *Ibanez v. Fla. Dep't of Bus. & Prof'l Reg.*, 512 U.S. 136, 146–49 (1994) (applying intermediate scrutiny, rather than *Zauderer*, to compelled disclaimer directed at non-misleading speech).

The Supreme Court has never suggested that *Zauderer* applies in other contexts. And a majority of the courts of appeals acknowledge this limit on *Zauderer*. *See Dwyer v. Cappell*, 762 F.3d 275, 282–83 (3d Cir. 2014) (holding that a compelled disclosure failed *Zauderer* because it "[was] not reasonably related to preventing consumer deception and [was] unduly burdensome"); *Greater Baltimore Ctr. for Pregnancy Concerns, Inc. v. Mayor & City Council of Baltimore*, 721 F.3d 264, 283 & n.8 (4th Cir. 2013) (holding that *Zauderer* applies only to "[d]isclosure requirements aimed at misleading commercial speech"); *Test Masters Educ. Servs., Inc. v. Robin Singh Educ. Servs., Inc.*, 799 F.3d 437, 453 (5th Cir. 2015) (holding that *Zauderer* applies only when compelled disclosures are "directed at deceptive or misleading commercial speech"), *rev'd in part on other grounds*, 2015 WL 13768849; *ECM BioFilms, Inc. v. FTC*, 851 F.3d 599, 616 (6th Cir. 2017) (holding that disclosure requirements "must be reasonably related to the [government's] interest in preventing deception of consumers" (quotation marks omitted)); *1-800-411-Pain Referral Serv., LLC v. Otto*, 744 F.3d 1045, 1062 (8th Cir. 2014) (applying the *Zauderer* standard only because the advertisements at issue were "inherently misleading on their face"); *Entm't Software*, 469 F.3d at 652 ("The Court has allowed states to require the inclusion of purely factual and uncontroversial information as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." (ellipsis and quotation marks omitted)); *United States v. Wenger*, 427 F.3d 840, 849 (10th Cir. 2005) (explaining that *Zauderer* "eases the burden of meeting the *Central Hudson* test" by "presum[ing] that the government's interest in preventing consumer deception is substantial").

The graphic-warnings requirement and the proposed rule fail to satisfy this test. Neither Congress nor FDA has suggested that graphic warnings are needed to combat "inherently misleading commercial advertisements." *Milavetz*, 559 U.S. at 250. And that is not surprising: federal law already prohibits tobacco product manufacturers from making false or misleading claims through cigarette packages or advertising. *See* 21 U.S.C. §§ 331(a), 387c(a)(1), (7). Instead of preventing consumer *deception*, FDA says that it wants to "promote greater public

understanding," 84 Fed. Reg. at 42,755, which is not remotely the same thing. Thus, FDA cannot rely on *Zauderer* here.

5. In any event, "promoting greater public understanding" is not a substantial interest.

Even if *Zauderer* were not limited to preventing consumer deception, it still requires that the government pursue a "substantial" interest. *See CTIA - The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 844 (9th Cir. 2019); *Am. Meat*, 760 F.3d at 34 (Kavanaugh, J., concurring in the judgment) (explaining that *Zauderer* requires the same type of "substantial" interest that *Central Hudson* requires); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 115 (2d Cir. 2001) (upholding, under *Zauderer*, a compelled disclosure based on the "substantial [state] interest in protecting human health and the environment"). FDA has failed to identify such an interest here.

To begin, FDA does not assert an interest in reducing smoking. It asserted such an interest in its first graphic-warnings rulemaking, but was forced to "essentially concede[]" that it "lack[ed] any evidence" that graphic warnings would further than interest. *R.J. Reynolds*, 696 F.3d at 1219–20. Rather, than re-litigating that issue, FDA has asserted a new interest: "promoting greater public understanding of the negative health consequences of cigarette smoking." 84 Fed. Reg. at 42,755.

That interest is not substantial. As then-Judge Kavanaugh has explained, under *Zauderer*, "it is plainly not enough for the Government to say simply that it has a substantial interest in giving consumers information." *Am. Meat*, 760 F.3d at 31 (Kavanaugh, J., concurring in the judgment). "After all, that would be true of any and all disclosure requirements." *Id.* In other words, classifying a purely informational interest as "substantial" would "drain" the *Zauderer* test of "any meaning in the context of compelled commercial disclosures." *Id.*

The D.C. Circuit reached the same conclusion the last time that FDA issued a graphic-warnings rule. There, "FDA assert[ed] an interest in 'effectively communicating health information' regarding the negative effects of cigarettes." *R.J. Reynolds*, 696 F.3d at 1221. The court concluded, however, that FDA's "attempt to reformulate its interest as purely informational is unconvincing, as an interest in 'effective' communication is too vague to stand on its own." *Id.* The court further held that "FDA's interest in 'effectively communicating' the health risks of smoking is merely a description of the means by which it plans to accomplish its goal of reducing smoking rates, and not an independent interest capable of sustaining the Rule." *Id.*

The D.C. Circuit's decision in *American Meat Institute* is not to the contrary. 760 F.3d at 23–25. There, the D.C. Circuit upheld a disclosure that required country-of-origin labeling for food. But the government's interest was not purely "educating consumers"; the government wanted to "support[] American farmers and ranchers against their foreign competitors." *Id.* at 33 (Kavanaugh, J., concurring in the judgment); *see also id.* at 23–25 (majority opinion). FDA does not purport to advance any such interest here.

FDA has made this problem even worse by focusing on "less-known health consequences of smoking." 84 Fed. Reg at 42,755. As explained below, an analysis of data from FDA's own Population Assessment of Tobacco and Health ("PATH") survey shows that knowledge of these less-known risks does not have a statistically significant effect on people's smoking behavior and

generally has no effect on people's overall risk assessment of smoking. *See infra* pp. 20–22. FDA is therefore asserting that it has a "substantial" interest in giving consumers information—*even though that information will not materially change their behavior (or even their overall view of the risks of smoking)*. In other words, FDA says it has a substantial interest in giving people information for information's sake. But "that would be true of any and all disclosure requirements." *Am. Meat*, 760 F.3d at 31 (Kavanaugh, J., concurring in the judgment). Such a malleable interest does qualify as "substantial" under *Zauderer*.

Moreover, FDA's assertion that it has a substantial interest in educating consumers about these "less-known health consequences" is belied by the Agency's own actions. Over the past several years, FDA has spent hundreds of millions of dollars running public-education campaigns, such as the *Real Cost*, *Fresh Empire*, *This Free Life*, and *Every Try Counts* campaigns. Steenkamp Report § 3.2(C)–(F). Yet FDA has not cited *any* evidence to show that these campaigns have addressed the smoking risks identified in the proposed graphic warnings. That omission is telling: if FDA truly believed that it had a substantial interest in educating consumers about these risks, then the Agency would have said something about them in these public-education campaigns.

FDA's cost-benefit analysis likewise confirms that the Agency lacks a substantial interest. In that analysis, FDA acknowledges that "there is a high level of uncertainty around quantitative economic benefits" and therefore chooses to "describe them qualitatively." Preliminary Regulatory Impact Analysis ("PRIA") at 2. In other words, FDA says *nothing* about whether the proposed rule's benefits exceed its costs—indeed, FDA says *nothing* about whether the proposed rule has *any benefits at all*. If the Agency had a substantial interest in providing this information to the public, it would presumably have been able to attach some concrete value to that information—or at a minimum, it would have attempted to do so.

6. Graphic warnings are "unjustified" because they would not remedy a real-world harm.

Under *Zauderer*, the government may not compel "unjustified" disclosures. *NIFLA*, 138 S. Ct. at 2377. Courts have identified two types of unjustified disclosures: First, a disclosure is unjustified if it fails to address a harm that is "potentially real" rather than "purely hypothetical." *Id.*; *see also Ibanez*, 512 U.S. at 146 (holding that a disclaimer requirement was "unjustified" because the state regulatory board "fail[ed] … to point to any harm that [was] potentially real, not purely hypothetical"). Second, a disclosure is unjustified if it fails to "remedy" that harm. *Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 525 (D.C. Cir. 2015) (concluding that a mandatory disclosure requirement regarding "conflict minerals" violated *Zauderer* because the rationale for the disclosure requirement was "entirely unproven and rest[ed] on pure speculation"). For example, as the Supreme Court recently underscored, a compelled disclosure cannot remedy a harm by telling people things that they "already know." *NIFLA*, 138 S. Ct. at 2377. The Tobacco Control Act's graphic-warnings requirement and the proposed rule flunk *Zauderer* on both accounts.

(a) The graphic-warnings requirement and the proposed rule are trying to solve a hypothetical problem.

FDA asserts that the proposed rule will address the public's lower rates of awareness of certain risks of smoking. But that is a purely hypothetical problem—indeed, it is a counterfactual,

because the public accurately perceives the danger of smoking (and indeed may even overestimate that danger).

1. Americans are "already surrounded by many high-quality sources of information regarding smoking." Klick Report ¶ 5.3. For decades, Congress has required that cigarette manufacturers display warning labels that inform the public that cigarette smoking can cause serious diseases and harm one's health. In 1965, Congress mandated that cigarette packages include the following warning: "CAUTION: Cigarette Smoking May Be Hazardous to Your Health." Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282, 283 (1965). In 1969, Congress adopted a new warning: "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health." Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87, 88 (1970). In Congress's view, this warning fully advised the public about the risk of smoking; thus, Congress provided that "[n]o statement relating to smoking and health, other than [this warning], shall be required on any cigarette package." *Id.* at 88. And in 1984, Congress required that all packaging and advertising include a series of rotating warnings that covered a variety of smoking risks:

- "SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

- "SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

- "SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

- "SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide."

Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200, 2201–02 (1984). These warnings likewise preempted all other warnings. *See* 15 U.S.C. § 1334 (1988).

In addition to warning labels, the public has received information about the risks of cigarettes from many other sources. Since 1964, the Surgeon General has issued thirty-three reports about the health risks of smoking. Klick Report ¶ 5.6. Federal agencies such as the CDC and FDA have run public-education campaigns. *Id.*; Steenkamp Report § 3.2. State and local entities have done likewise. Klick Report ¶ 5.7. People also receive "substantial information regarding smoking from their doctors and other health professionals." *Id.* ¶ 5.9. "Public health organizations, including the American Cancer Society, the American Heart Association, and the American Lung Association, have also communicated smoking-related risks to consumers in many media, including broadcast media campaigns, pamphlet, and advertisements." *Id.* ¶ 5.10 (footnotes omitted). "[I]nsurance companies invest significant resources in educating their customers about the dangers of smoking in addition to providing support for cessation." *Id.* ¶ 5.10. And schools educate minors about the risks of smoking. *See* CDC, *Guidelines for School Health Programs to Prevent Tobacco Use and Addiction* (1994), https://tinyurl.com/y53dmhqf; FDA's Center for Tobacco Products, *Prevention Through Public Education* (Sept. 24, 2019) ("Campaign ads and other prevention resources are strategically placed where teens spend the majority of their time,

both online and in school. FDA also teamed up with Scholastic to create curriculum about e-cigarettes for high school teachers.").

2. As a result of these warning labels and public-health campaigns, the public already understands that smoking cigarettes is harmful. PATH data show that 99.5% of individuals believe that cigarette smoking is harmful to health, with 91% believing that it is "very or extremely harmful," 7% believing it is "somewhat harmful," and 1.5% believing it is "slightly harmful." Klick Report ¶ 5.20. Put differently, only 0.5% of people believe that smoking is *not* harmful at all, and only 1.5% believe it is "slightly harmful."

How harmful do you think cigarettes are to health?
PATH Survey

Waves 1-3
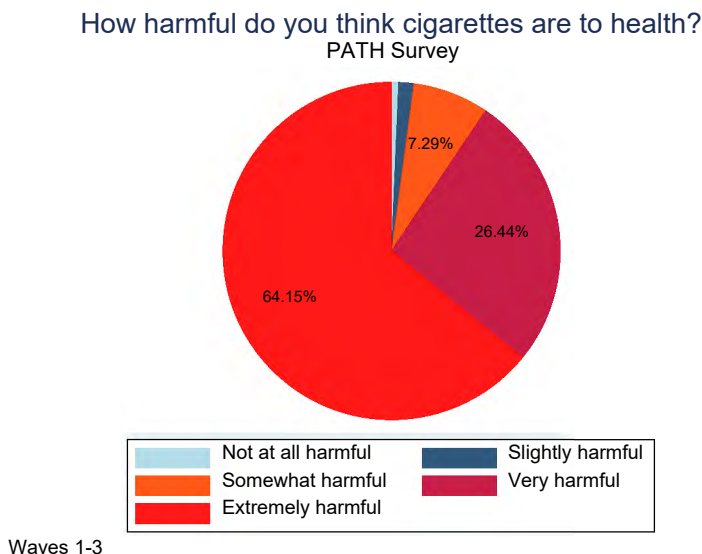
In addition, from 2002 to 2018, Gallup polls found that 81.5% of respondents believe that smoking is very harmful, and another 14% believe it is somewhat harmful. *Id.* ¶ 5.26.

It would be difficult, if not impossible, to improve these numbers. Experts generally agree that, "[a]s a practical matter, getting to awareness levels above 80 or 90 percent is unrealistic." *Id.* ¶ 5.17. Indeed, more people know that smoking is harmful to health than know that the Earth revolves around the sun (74%), or where the United States is on a map (94%). *See* Nat'l Sci. Found., *Science and Engineering Indicators* 7-23 (2014), https://tinyurl.com/y3ojlwu4; Nat'l Geographic Educ. Found., *2006 Geographic Literacy Study* 26 (2006), https://tinyurl.com/y35yaj2t. Thus, the data described above show that the public universally understands that smoking is harmful.

Data also show that the public is universally aware of the major risks of cigarettes. For example, PATH data show that 94% of individuals believe that smoking causes lung cancer, 94% believe that smoking causes lung disease, and 88% believe that smoking causes heart disease. *See* Klick Report ¶¶ 5.41, 5.43, 5.48.

3. In the proposed rule, FDA acknowledges that the public universally understands the major risks of smoking. For example, the proposed rule does not include warnings that "Cigarettes are addictive," that "Smoking can kill you," or that "Quitting smoking now greatly reduces serious risks to your health," because the public already knows those things. *See* 84 Fed. Reg. at 42,767

n.5, 42,772. The proposed rule also does not include a warning about lung cancer—presumably because FDA believes that the public already knows about that risk.

Moreover, FDA expressly concedes that the public knows about the risks described in the nine warning statements required by the Tobacco Control Act. FDA acknowledges that there are "recent studies conducted in the United States that failed to find an effect of pictorial cigarette warnings on increasing health beliefs about the negative effects of smoking." 84 Fed. Reg. at 42,763 (citing Brewer et al. 2018, Byrne et al. 2017, Niederdeppe et al. 2019, Skurka et al. 2018). FDA attributes that failure to the "high pre-existing level of knowledge of the specific health consequences described in the warnings tested in those studies." *Id.* at 42,764. Importantly, those studies tested all nine of the Act's warning statements—which means that, in FDA's view, the public has such a "high pre-existing level of knowledge" about the risks described in the Act's warning statements that graphic warnings cannot increase the public's knowledge any further. FDA has therefore conceded that that the public universally knows that "Tobacco smoke can harm your children," "Cigarettes cause fatal lung disease," "Cigarettes cause cancer," "Cigarettes cause strokes and heart disease," "Smoking during pregnancy can harm your baby," and "Tobacco smoke causes fatal lung disease in nonsmokers." *See also* 84 Fed. Reg. at 42,767–68 (acknowledging that, in FDA's first consumer research study, "relatively few participants reported that the content of the TCA statements was new information").

Not only does the public understand these risks, the public actually *overestimates* many of them. For example, in one study, smokers and non-smokers alike "substantially over-estimated the lung cancer rate of smokers, as well as the contribution of smoking to over-all mortality and expected losses in lifespan." Klick Report ¶ 5.71. Thus, FDA cannot assert an interest in increasing the public's understanding of these risks.

4. FDA tries to sidestep this problem by adopting warnings that allegedly focus on "less-known health consequences of smoking." 84 Fed. Reg at 42,755. But the proposed rule fails to demonstrate that the public does not already understand these risks.

Once again, PATH data and other surveys show that the public is universally aware of almost all of the risks that FDA describes as "less-known." For example:

- 94% of people believe that smoking causes lung disease. Klick Report ¶ 5.48.

- In 2017, 93% of people listed tobacco as a risk factor for cancer. *Id.* ¶ 5.50.

- 91% of people believe that cigarette smoke can harm your children. *Id.* ¶ 5.59.

- 88% of people believe that smoking causes heart disease and 80% believe that smoking causes stroke. *Id.* ¶¶ 5.43, 5.45.

- 86% of people agreed that smoking causes harm to fetuses. *Id.* ¶ 5.58.

- 83% of people believe that second-hand smoke causes lung disease in non-smokers. *Id.* ¶ 5.60.

- 82% of people believe that smoking causes circulation problems. *Id.* ¶ 5.47.

Surprisingly, FDA does little to demonstrate that the public does not already know about these risks of smoking. In the proposed rule, FDA asserts that "findings in the scientific literature demonstrate that the U.S. public—including youth and adults, smokers and nonsmokers—holds misperceptions about the health risks caused by smoking." 84 Fed. Reg. at 42,756. But FDA's citations do not back up that claim. For example, FDA repeatedly relies on studies that are nearly or more than a decade old and say *nothing* about the current state of the public's knowledge. *See id.* at 42,761 (citing five articles based on 2001 studies, one article based on a 2002 study, one article based on a 2004 study, one article based on a 2008 study, and three articles based on 2010 studies). FDA also repeatedly relies on studies of the populations of other countries, such as Canada, China, Singapore, Scotland and the United Kingdom. *See id.* And FDA relies on multiple studies that discuss health risks (such as cervical cancer, infertility, kidney cancer, and osteoporosis) that are not addressed in the proposed warnings. *See id.* None of these studies shed any light on the relevant question: what does the U.S. population currently know about the health risks identified in the proposed warnings?

FDA relies on only a handful of studies that address that question. And several of those studies actually show that the public *does* understand the health risks identified in the proposed warnings. For example, FDA relies on a 2015 study showing that 94.6% of people know that smoking causes throat cancer, 83.3% of people know that smoking causes oral cancer, 93.1% of people know that smoking causes mouth cancer, 82.1% of people know that smoking causes esophagus cancer, and 60.6% of people know that smoking causes lip cancer. *See id.* That study therefore undermines, rather than supports, FDA's assertion that people do not understand that smoking causes head and neck cancer. *See also id.* (relying on a 2010 study showing that "[p]articipants knew about the risk of [low birth weight] and premature birth, supporting previous research on the topic").

Moreover, FDA cannot rely on its consumer research studies to demonstrate that the public does not know about these risks. As an initial matter, these surveys suffer from methodological problems that prevent FDA from relying on them. *See infra* pp. 41–42. In addition, these surveys lack virtually any relevant information about the public's knowledge. Those surveys asked respondents (among other things) whether FDA's proposed graphic warnings contained "new information" and whether respondents "learned something" from the warnings. 84 Fed. Reg. at 42,771. But these "new information" and "self-reported learning" measurements are virtually meaningless. Both questions are dripping with social-desirability bias: FDA's surveys plainly convey to respondents that they are supposed to say that the warnings contain "new information" and that the respondents "learned something." This is clearly illustrated by the results that FDA got when it asked these questions about the 35-year-old, universally known Surgeon General's warnings: 27.9% of people said that they contained "new information" and the "mean rating of self-reported learning … was 3.02" on a scale of 1 (learned nothing) to 7 (learned very much). Such high results demonstrate that FDA's questions are irredeemably flawed.

In addition, FDA's first consumer research study calls into doubt whether the proposed warnings actually convey any new information. As explained above, FDA concedes that the Tobacco Control Act's warnings cannot meaningfully increase the public's understanding about the risks of smoking because "the public already has a high pre-existing level of knowledge" about those risks. *See supra* p. 15. And FDA's first consumer research study suggests that the proposed warnings fare little better. That survey analyzed whether respondents thought that FDA's proposed textual warnings were more "informative" than the Tobacco Control Act's textual warnings. Only two of the proposed textual warnings passed that test. *See* Study 1 Results Report at 3-11. If the Act's textual warnings are universally understood (as FDA concedes), and the proposed textual warnings are not any more informative, it stands to reason that the proposed textual warnings are likewise universally understood.

Tellingly, FDA is silent about other measures that could show whether the public understands these risks. For example, FDA could have relied on the PATH data discussed above: after all, the PATH survey was "started explicitly to inform the FDA's regulatory decisions and actions with respect to smoking." Klick Report ¶ 5.18. But FDA ignored that evidence, which shows that the public universally understands almost all of these risks. In addition, at the beginning of FDA's second consumer research study, the Agency asked respondents whether smoking caused the diseases that are mentioned in the warnings. But FDA has not released that data—perhaps because the data show that FDA was trying to solve a hypothetical problem.

5. Most importantly, FDA effectively *concedes* that the public already knows about many of the risks identified in the proposed warnings.

To begin, take the two textual warning statements that FDA retained from the Tobacco Control Act: "Tobacco smoke can harm your children" and "Tobacco smoke causes fatal lung disease in nonsmokers." 84 Fed. Reg. at 42,797. As explained above, FDA has conceded that "the public already has a high pre-existing level of knowledge of the[se] specific health consequences," 84 Fed. Reg. at 42,764, and that showing these warnings to people will not increase their understanding. *See supra* p. 15. Given that everyone "already know[s]" this information, these warnings are unjustified. *NIFLA*, 138 S. Ct. at 2377.

In addition, several of the proposed warnings do not convey any relevant information beyond what the Tobacco Control Act's warnings conveyed. For example, one of the Act's warnings says that "Cigarettes cause strokes and heart disease." 15 U.S.C. § 1333(a)(1). FDA's proposed warning repeats virtually the same information: "Smoking can cause heart disease and strokes by clogging arteries." 84 Fed. Reg. at 42,797. The proposed warning conveys the exact same information about the *risk* of smoking cigarettes (that it can cause strokes and heart disease) and then conveys a granular piece of information about how the risk operates (by clogging arteries). Even if this disease *mechanism* is new information to some people, FDA has not shown (and cannot show) that adding this granular piece of information affects the public's understanding about the *risks* of smoking.

As another example, one of the Act's warnings says that that "Cigarettes cause fatal lung disease." 15 U.S.C. § 1333(a)(1). Again, FDA's proposed warning repeats virtually the same information: "Smoking causes COPD, a lung disease that can be fatal." 84 Fed. Reg. at 42,797. As before, the proposed warning does not convey any additional information about the *risk* of smoking

cigarettes; it simply names the "fatal lung disease" that is described in both warnings. Moreover, it is not clear that much of the public will know what COPD is, thus making the proposed warning unnecessarily complex and less meaningful. The same analysis largely applies to the proposed warning "Smoking causes head and neck cancer," which conveys little beyond the Act's warning "Cigarettes cause cancer," and the proposed warning "Smoking during pregnancy stunts fetal growth," which conveys little beyond "Smoking during pregnancy can harm your baby." *Compare* 15 U.S.C. § 1333(a)(1), *with* 84 Fed. Reg. at 42,797.

In short, the evidence shows that the public "already knows" about the major risks of smoking *and* many of the risks identified in the proposed warnings. *NIFLA*, 138 S. Ct. at 2377. FDA nevertheless insists that the public needs to be warned about these risks, and graphic warnings are the only way to do so. That is a solution in search of a problem, and it is "unjustified" under *Zauderer*. *See NIFLA*, 138 S. Ct. at 2377.

> **(b)** **Even if the public did not understand these risks, FDA has not shown that graphic warnings would increase the public's understanding.**

The evidence demonstrates that FDA has not shown that the public lacks relevant information about the risks of smoking. But even if FDA could make such a showing, the Agency has not shown that graphic warnings would address that problem.

1. As explained above, graphic warnings evoke negative emotions such as fear, shame, and disgust. *See supra* Section I.B.1. But the "empirical evidence on the use of emotional appeals in warnings is mixed at best." Klick Report ¶ 5.81. As Dr. Martin explains, "[n]euroscience supports the [conclusion] that smokers have a strong tendency to avoid high-threat messages." Martin Report at 5. Dr. Martin's clinical experience confirms that fact: "Through additional interviews, we found that the smokers were already aware of those risks and chose to avoid thinking about them to the point of rejecting, and becoming irritated by, the message as well as the messenger." *Id.* at 6.

Professor Joannes Evangelista Steenkamp, who is an expert in marketing communications, agrees with Dr. Martin. As Professor Steenkamp explains, a "negative emotion like fear" can undermine a message's effectiveness. Steenkamp Report at 17. A high level of fear "produces inhibiting effects," which may cause the audience to "emotionally block the message by tuning out, perceiving it selectively, or denying its arguments outright." *Id.* Thus, "[r]esearch has shown that anti-smoking messages and graphic health warnings using high levels of fear were ineffective because they led to defensive tendencies such as message avoidance and interfered with the processing of recommended solutions." *Id.*

Because of these dynamics, multiple studies have concluded that graphic warnings do not change people's beliefs about the harms of smoking. *See, e.g.*, Brewer et al. 2018, at 238; Byrne et al. 2017, at 313; Byrne et al. 2015, at 686–88, 690; Niederdeppe et al. 2019, at 47; Skurka et al. 2018, at 863; Sussenbach et al. 2013, at 1202.

2. FDA tries to demonstrate that the proposed warnings would increase the public's knowledge by relying on its second consumer research study. FDA begins by arguing that the

proposed warnings "demonstrate statistically significant improvements, as compared to the control condition (i.e., the Surgeon General's warnings), on both the outcomes of 'new information' and 'self-reported learning' (i.e., knowledge gain)." 84 Fed. Reg. at 42,772 n.10. FDA then argues that "the outcomes 'new information' and 'self-reported learning' are predictive for the task of identifying which of the cigarette health warnings increase understanding of the negative health consequences of cigarette smoking." *Id.* at 42,772. But this survey is deeply flawed.

First, as explained further below, FDA's surveys suffer from methodological problems that prevent FDA from relying on them. *See infra* pp. 41–42.

Second, because FDA's second survey tested the new textual statements and the graphic images *in combination*, there is no basis to think that the supposed improvements are attributable in any way to the graphic components of the proposed warnings, rather than to the new text.

Third, the survey does not actually demonstrate that the proposed warnings convey new information to the public. As explained above, the "new information" and "self-reported learning" questions are infected with social-desirability bias, which makes them unreliable. *See supra* pp. 16–17. And FDA's first consumer research study demonstrates that the proposed warnings are no more "informative" than the Tobacco Control Act's warnings, which calls into question whether they actually convey any new information at all. *See supra* p. 17.

Fourth, even if the proposed warnings convey *some* new information, FDA has not shown that they convey *enough* information to meaningfully change how the public thinks about smoking. FDA says that it is "including in th[e] proposed rule only the warnings that demonstrate statistically significant improvements, as compared to the control condition (i.e., the Surgeon General's warnings) on both the outcomes of 'new information' and 'self-reported learning' (i.e., knowledge gain)." *Id.* at 42,772. But that is an exceedingly low bar. FDA repeatedly says that smokers see the Surgeon General's warnings "over 5,100 times per year," and that those warnings "have not changed in nearly 35 years." *Id.* at 42,756, 42,759. And as already discussed, FDA effectively concedes that knowledge of those warnings is universal. *See supra* pp. 14–15. In other words, FDA's justification for including a warning in the proposed rule is merely that the warning conveyed more "new information" than the universally understood, 35-year-old Surgeon General's warnings that smokers see literally thousands of times per year.

Fifth, FDA's second consumer research study does not demonstrate that the warnings will help the public *learn* anything. FDA focused on the "new information" and "self-reported learning" measurements because the Agency believes that "people are more likely to pay attention to information that is new," and because getting individuals to notice and pay attention to the warnings is the "first step" to increasing public understanding. 84 Fed. Reg. at 42,765. But there is a *second step* to increasing public understanding—individuals must "mentally store[] the information" and "give[] meaning to [it]," so it can be remembered later. *Id.* at 42,760; *see also id.* ("How much the information is mentally processed, reflected on, and thought about impacts how well the information is learned and understood."). And notably, FDA *does not say* that the graphic warnings will help the public with that second step. At best, therefore, FDA has shown that the graphic warnings *might* help with the first step of a two-step process. That is not sufficient to show that graphic warnings will actually "remedy" a harm.

FDA's second consumer research study confirms the point. In that study, FDA tested respondents' knowledge about the health risks of smoking ("Session 1"), showed respondents the proposed warnings, and then tested their health beliefs again after one day ("Session 2") and after fourteen days ("Session 3"). *Id.* at 42,771–72. At the end of that process, five of the warnings actually *reduced* the respondents' knowledge about the relevant health risks, and seven of the remaining eight warnings saw sharp decreases in knowledge gains between Session 2 and Session 3. *See* Study 2 Results Report at 3-10 to 3-17 (showing drops between Session 2 and Session 3 of 76%, 66%, 55%, 50%, 50%, 40%, and 34%).

FDA's decision not to rely on these statistics is telling. FDA asserts that "warning statements focused on less-known health consequences of smoking paired with concordant color graphics would promote greater public understanding of the risks associated with cigarette smoking." 84 Fed. Reg. at 42,755. The best way to measure whether the proposed warnings actually would advance that interest is to show people the warnings, and then measure their health beliefs at some point in the future. FDA tried to do that here, and the warnings either *reduced* people's knowledge, or had only a fleeting impact that quickly started wearing off. So FDA decided to focus on a *different* measurement, one that was (supposedly) more favorable, but far less relevant to the question at hand. That is an implicit admission that FDA cannot prove that the warnings will actually increase public knowledge about the risks of smoking.

Sixth, even if the warnings helped the public learn something, the survey does not show *what* the public will learn. On this point, FDA inexplicably failed to ask the crucial questions: the Agency asked whether the warnings conveyed new information, but failed to ask *what* information people thought was new; the Agency also asked whether people learned something from the warnings, but failed to ask *what* people learned. Given the emotional, ideological, and misleading nature of the warnings, it is entirely possible that people "learned" something that is wrong, or something that is unrelated to the risks of smoking. *See supra* Sections I.B.1–2.

3. As the evidence above demonstrates, FDA cannot show that the proposed warnings will increase the public's understanding about the health risks of smoking. But there is an even deeper problem with those warnings: FDA cannot show that they will meaningfully change how the public thinks about the overall risks of cigarettes.

FDA says that the "proposed warnings are intended to promote greater public understanding of the negative health consequences of cigarette smoking." 84 Fed. Reg. at 42,755. As a logical matter, when people think about those consequences, they look at all of the individual risks of smoking and use them to form an impression of the overall risk. In that process, not all risks are treated equally: some risks are large and some are small, and unsurprisingly, people tend to give more weight to the larger risks and less weight to the smaller risks. Indeed, in some cases, people may not give *any* weight to a particular risk of smoking. As Dr. Klick explains, "if more important or severe risks do not sway a decision, lower level risks will not either." Klick Report ¶ 4.6. Thus, "for those who know smoking is deadly but are still inclined to smoke, risks like blindness and erectile dysfunction are likely not material." *Id.* ¶ 8.1.

Here, Dr. Klick analyzed PATH data to determine whether smokers find the risks identified in the proposed warnings to be material. The PATH survey measures respondents' knowledge of specific smoking risks (including many of the risks identified in the proposed warnings), their

assessment of the overall risk of smoking, and their decision whether to smoke. Using that data, Dr. Klick ran a regression analysis to answer the following question: "[I]f an individual who already believes smoking is extremely harmful to his health but continues to smoke, suddenly becomes aware of a new specific risk, how likely is it that the new risk knowledge induces him to stop smoking?" *Id.* ¶ 5.31.

Dr. Klick reported the results as odds ratios, which describe the likelihood that someone who agrees that smoking poses a particular risk will nevertheless smoke. *See Id.* ¶ 5.33 n.43. An odds ratio "greater than one implies that one who agrees with the risk is more likely to smoke than the person who does not agree with the risk," and a ratio less than one "implies that one who agrees with the risk is less likely to be a smoker than one who does not agree with the risk." *See id.* Dr. Klick's results overwhelmingly demonstrate that the risks described in the proposed warnings do not have *any* effect on people's overall risk assessment or smoking behavior:

Effect of General Harm Assessment on Smoking Likelihood		
Fixed Effects Logistic Regression		
	Odds Ratio	Odds Ratio
How harmful do you think cigarettes are to health (1-5)	0.56 $p < 0.01$	
Indicated cigarettes are very or extremely harmful to health		0.38 $p < 0.01$
Agree that second-hand smoke can cause lung disease in non-smokers	1.00 Not statistically significant	0.99 Not statistically significant
Agree that smoking causes bladder cancer	1.11 Not statistically significant	1.10 Not statistically significant
Agree that smoking causes harm to unborn fetuses from second-hand smoke	0.96 Not statistically significant	0.98 Not statistically significant
Agree that smoking causes heart disease	0.87 Not statistically significant	0.86 Not statistically significant
Agree that smoking causes stroke	1.07 Not statistically significant	1.07 Not statistically significant
Agree that smoking causes lung disease	0.92 Not statistically significant	0.90 Not statistically significant

Effect of General Harm Assessment on Smoking Likelihood		
Agree that smoking causes poor circulation	0.82 Not statistically significant	0.79 Not statistically significant
Agree that smoking causes blindness	0.98 Not statistically significant	0.99 Not statistically significant
Individual Fixed Effects	Yes	Yes
Wave Fixed Effects	Yes	Yes
The outcome variable is a 0-1 indicator denoting whether the individual currently smokes cigarettes. Data from waves 1-3 are used in the estimation. The conditional logit model is used for estimation ("clogit" in Stata). Regressions are weighted according to the PATH longitudinal weights averaged for each person over the three waves. Standard errors are clustered at the individual level.		

Based on his analysis, Dr. Klick concluded that a person's awareness of the individual risks surveyed in the PATH data has no statistically significant effect on smoking behavior, and generally has no effect on the person's overall risk assessment of smoking. *Id.* ¶ 5.36. Once again, FDA deliberately chose *not* to rely on this data, even though the PATH was "started explicitly to inform the FDA's regulatory decisions and actions with respect to smoking." *Id.* ¶ 5.18.

This analysis is devastating for the proposed rule. As explained above, FDA does not have a substantial interest in giving people information. *See supra* Section I.B.5. That is all the more true when that information is *immaterial* to the people receiving it. Dr. Klick's analysis shows that the information in the proposed warnings will have no effect on people's decision whether to smoke, and generally will not even affect their overall assessment of the risks of smoking. Thus, FDA does not have a substantial interest in compelling manufacturers to deliver that information through gruesome, disturbing images that are designed to frighten their customers.

In sum, the evidence shows that, even if the proposed warnings increase the public's knowledge about the risks of smoking, the warnings will not change how the public thinks about the overall risks of cigarettes or affect smoking behavior. Such a useless transfer of information does not satisfy *Zauderer*'s requirement that the compelled speech "remedy" a real-world harm.

(c) FDA cannot show that graphic warnings will reduce smoking.

FDA does not assert that the proposed graphic-warnings rule would reduce smoking, and the Agency's previous analysis demonstrates that any such claim would be wrong.

In the first graphic-warnings rule, FDA argued that the warnings would "decrease smoking initiation and increase smoking cessation." *Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36,628, 36,719 (June 22, 2011). But FDA failed to produce even a "shred of evidence" that the warnings would have that effect. *R.J. Reynolds*, 696 F.3d at 1219. Indeed, FDA's own study determined that the warnings would reduce smoking rates by a mere

0.088%, a number that FDA conceded was statistically indistinguishable from zero. 76 Fed. Reg. at 36,775–76. As FDA explained: "our effectiveness estimates are in general not statistically distinguishable from zero; we therefore cannot reject, in a statistical sense, the possibility that the rule will not change the U.S. smoking rate. Therefore, the appropriate lower bound on benefits is zero." *Id.* at 36,776; *see also* Ngo et al. 2018, at 6; Shang et al. 2017, at 10.

Nothing has changed in the past eight years—there is still no evidence that the warnings will reduce smoking. Smoking prevalence and cigarette consumption have "generally declined over the past several decades." 84 Fed. Reg. at 42,758. Between 1965 and 2017, the percentage of adults who smoked cigarettes fell from 42.4% to 14%. *Compare* U.S. Dep't of Health and Human Servs., Office of the Surgeon General, *The Health Consequences of Smoking—50 Years of Progress* 720 (2014), https://tinyurl.com/y54j8anx ("HHS 2014") (42.4%), *with* CDC, *Current Cigarette Smoking Among Adults in the United States* (last updated Feb. 4, 2019), https://tinyurl.com/jdqoxrq (14%). Between 1981 and 2017, the number of cigarettes purchased annually in the United States dropped from 640 billion to 249 billion—a decline of more than 60% despite an increase in the U.S. population of more than 100 million. *Compare* CDC, *Surveillance for Selected Tobacco-Use Behaviors—United States, 1900–1994* (Nov. 18, 1994), https://tinyurl.com/yxoxxrrn (640 billion), *with* CDC, *Economic Trends in Tobacco* (last updated July 23, 2019), https://tinyurl.com/y8y599kb (249 billion). And between 1997 and 2018, the percentage of high school students who smoked fell from 36.4% to 8.1%. *Compare* HHS 2014 (36.4%), *with* CDC, *Youth and Tobacco Use* (last updated Feb. 28, 2019), https://tinyurl.com/jvsmmen (8.1%); *see also 2018 National Survey on Drug Use and Health*, https://tinyurl.com/y4amqfss (finding that, in 2018, 2.7% of adolescents aged 12 to 17 smoked cigarettes in the past month).

FDA cannot demonstrate that graphic warnings would cause smoking to decline any faster than it already has. On the contrary, the evidence suggests that graphic warnings would not meaningfully affect smoking rates. As Dr. Klick demonstrates, there is no evidence that the presence of graphic warnings in Australia, Canada, and the United Kingdom produced a reduction in smoking among adults or youth in those countries. Klick Report ¶¶ 6.11–6.26. For example, Canada adopted a graphic-warnings rule in 2001. *Id.* ¶ 6.14. Since that time, however, smoking in Canada has declined at virtually the same rate as in the United States: 0.486% per year for Canada and 0.492% per year for the United States. *Id.* The same thing is true of Australia and the United Kingdom.

Smoking Prevalence Rates
U.S., Canada, Australia, U.K.
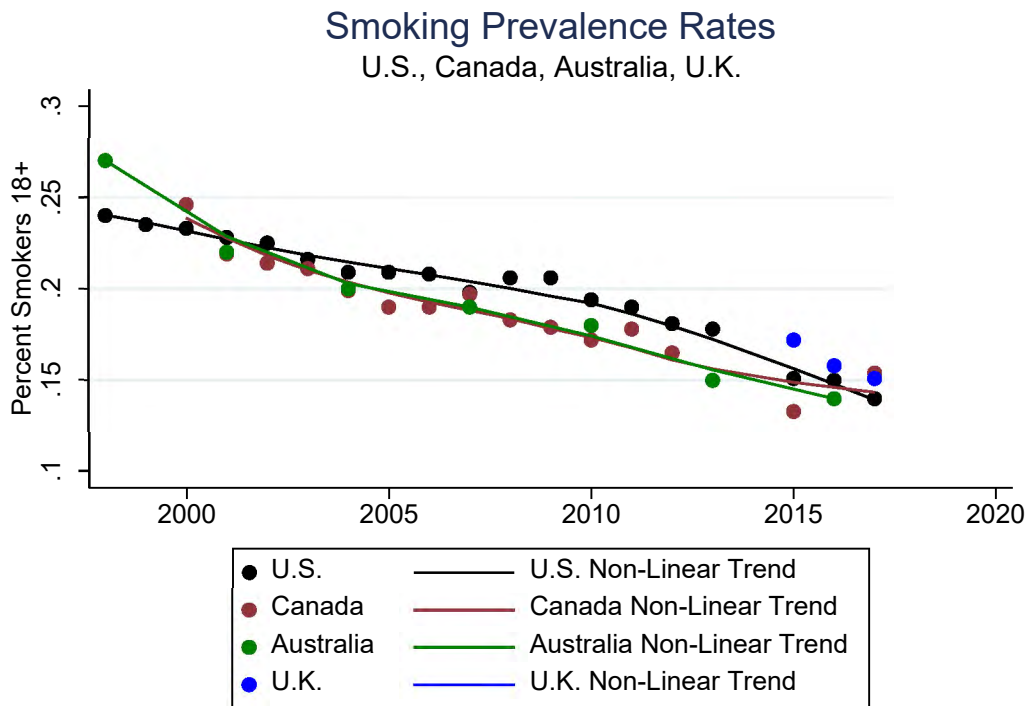
Moreover, few studies have even *attempted* to demonstrate that graphic warnings would reduce smoking, much less proved that they would do so. RAIS submitted a Freedom of Information Act request for government-funded graphic-warnings research, and even the researchers who applied for government funding candidly admitted that "there is limited research on the effectiveness of graphic warning labels for reducing actual smoking rates." *See* Dr. Daniel D. Langleben, *Application for Federal Grant from the National Institutes of Health* (submitted on Oct. 29, 2012) (attached as Exhibit N). Little has changed since the researchers made that admission. *See, e.g.*, Brewer et al. 2016, at 153 ("While a large experimental literature has developed, these experiments use very brief exposure to warnings; assess non-behavioural short-term outcomes, such as attitudes or quit intentions, instead of smoking behavior; and, yield results that need corroboration outside of a controlled research setting.").

This lack of evidence is unsurprising. As Dr. Martin explains, studies that focus on actual smoker behavior demonstrate that smokers quit because of self-motivation and self-efficacy, which is a "belief in one's ability to change a behavior." Martin Report at 4. And fear-based warnings actually weaken people's motivation to change and their belief that they can do so. *See id.* In addition, fear-based warnings cause many smokers to perceive that their "freedoms are being threatened, taken away or restricted." *Id.* at 3. When faced with such a threat, many smokers "behave in a manner that is … the opposite from the encouraged behavior." *Id.* at 3–4. As Dr. Martin explains, "confrontation of almost any kind tends to produce an opposing reaction in the targeted individual," leading to "equal or greater levels of resistance." *Id.* at 3.[4]

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[4] *See also* Robert Hornik, *Application For Grant Funding From The National Institutes Of Health* (Oct. 21, 2011) ("Terror management theory (TMT) suggests that fear appeals that make the mortality of the target audience

As a result, fear-based warnings are "not related to a successful behavioral outcome and in many smokers cause[] the opposite effect." *Id.* at 4; *see also* Klick Report ¶ 5.81 ("[E]mpirical evidence on the use of emotional appeals in warnings is mixed at best, and substantial literature suggests that fear-based warnings are not generally effective in changing actual behavior."). Indeed, an "established body of clinical, experimental and theoretical literature from the fields of health, addiction and motivation demonstrates the negative effects of extreme warnings, threats and fear communications in attempting to change motivation and behavior." Martin Report at 3; *see also* Klick Report ¶ 5.82 ("Some studies find that [fear-based] warnings may increase the incidence of the behaviors they are trying to discourage."). Dr. Martin therefore concludes that "FDA's graphic warnings campaign will likely harm public health through weakening motivation and impeding overall quitting in a significant portion of the smoking population." Martin Report at 2.

7. Graphic warnings are "unduly burdensome" because they are broader than reasonably necessary.

Under *Zauderer*, a compelled disclosure cannot be "unduly burdensome." *NIFLA*, 138 S. Ct. at 2377. A compelled disclosure fails that test if it is "broader than reasonably necessary." *Id.* And to show that a disclosure is not broader than reasonably necessary, the government has the burden of proving that less-restrictive means are not sufficiently effective. *See, e.g., id.* at 2376 ("California argues that it has already tried an advertising campaign, and that many women who are eligible for publicly-funded healthcare have not enrolled. But California has identified no evidence to that effect."); *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1143 (D.C. Cir. 2009) (per curiam) ("Although the standard for assessing burdens on commercial speech has varied, the Supreme Court's bottom line is clear: the government must affirmatively demonstrate its means are 'narrowly tailored' to achieve a substantial government goal." (citations omitted)). For example, the Ninth Circuit recently held that a government-mandated warning label that took up 20% of advertisements was "unduly burdensome" because a study showed that smaller warnings would accomplish the government's goals. *See Am. Beverage*, 916 F.3d at 757. The Tobacco Control Act's graphic-warnings requirement and the proposed rule fail the "unduly burdensome" test.

a. Under the proposed rule, each cigarette package must bear a graphic warning that takes up the top 50% of the package's front and rear panels. *See* 15 U.S.C. § 1333(a)(2). The warnings have two components: a textual warning statement, and a large color image that depicts the "negative health consequences of smoking." *See id.* § 1333(a)(1), (d). These requirements impose a heavy burden in four primary ways.

First, by taking up fully half of a cigarette package's front and rear panels, the graphic warnings would drastically limit the physical space that manufacturers have to communicate. Claxton Declaration ¶ 16 (attached as Exhibit L). This requirement would force manufacturers to

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salient may function differently than do other types of threat. TMT holds that when faced with one's mortality, people seek to manage the distress produced by focusing inward on their core values, world-view and ideology. In studies that apply TMT to behavior change, appeals that activate the target's mortality salience can boomerang in contrast to other appeals but only for those for whom the behavior being targeted is a part of their world view central to their self-esteem. By making mortality salient, those seeing the behavior as a part of their core identity can respond by defending their identity and dismissing the persuasive appeal as irrelevant or incredible.").

redesign both the front and back of their cigarette packages, thus interfering with trademarks and trade dress. Claxton Declaration ¶ 18. For example, the graphic warnings will materially impair RAIS's use of the "iconic Camel logo," which it has "used in various ways to identify the brand since 1913." Claxton Declaration ¶ 18.


Current pack front   *Modified pack front*

Manufacturers cannot respond to the proposed rule by simply shrinking their brand information to half its current size. Under applicable state and federal law, tobacco products generally must be displayed several feet behind a sales counter. *See, e.g.*, 21 C.F.R. § 1140.16(c); Claxton Declaration ¶ 24. Because cigarette packages are set so far back, substantially reducing the size of the message on those packages would make the message extremely difficult to read. Indeed, if manufacturers had 50% less space on the front and back of cigarette packages for conveying messages, the words on those packages would quickly become illegible and—for all practical purposes—invisible. Claxton Declaration ¶ 25.

Second, the proposed rule exacerbates this problem by taking up the *top* 50% of the package's front and rear panels. The top of the package is naturally the most prominent, so even under the best-case scenario, the proposed rule would lead consumers to focus on the graphic warnings instead of the manufacturer's message. Claxton Declaration ¶ 16. But in many cases, the effect will be far worse. As the image below reflects, many retail outlets arrange cigarette packages so only the top portion is visible. Claxton Declaration ¶ 25. This common method of displaying cigarettes allows consumers to see only the top part of the package, which would mean that consumers see *only* the graphic warnings. Claxton Declaration ¶ 26.
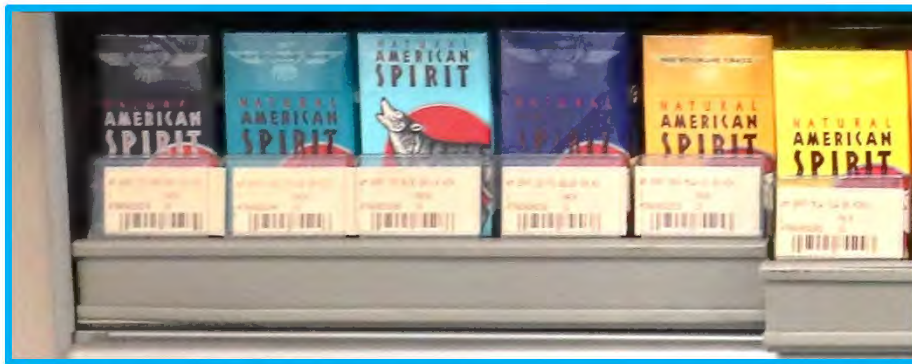
Current Retail Display
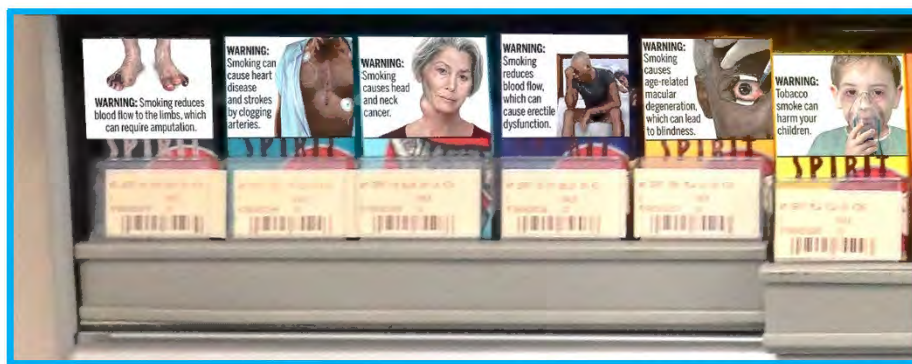
Modified Retail Display Reflecting Proposed FDA Rule

Third, the graphic images themselves will make it harder for manufacturers to effectively convey information to consumers. FDA has proposed to adopt thirteen graphic images that depict the "negative health consequences of smoking." 15 U.S.C. § 1333(d). These images are plainly designed to evoke feelings of fear and disgust in consumers, disparage that product, and convey the government's message that people should not smoke cigarettes. *See supra* Section I.B.1. That will have one of two effects: either the images will pull consumers' attention away from manufacturers' message or the images will repulse consumers and potentially cause them to avoid looking at cigarette packaging at all. Either way, the graphic images impose a heavy burden on manufacturers' speech. Claxton Declaration ¶ 15.

Fourth, the combination of these factors—gruesome images that take up the top 50% of the front and back of cigarette packages—will make all cigarette packages look substantially the same. That makes it more difficult for manufacturers to "differentiate their brands from competitors' brands," Claxton Declaration ¶ 12, which in turn makes it harder "to succeed in the marketplace," Claxton Declaration ¶ 4.

Current Retail Display

Modified Retail Display Reflecting Proposed FDA Rule
(Yellow Shading Reflects Additional 20% Required Graphic Warnings)

The combined effect of these requirements would harm cigarette manufacturers' ability to communicate with their consumers. The proposed rule would seize a huge portion of every cigarette package to convey the government's own anti-smoking message. That message would occupy the most prominent part of the package—and often the only part of the package that consumers could see. Thus, when adult cigarette consumers look at a pack of cigarettes, they will see only one thing: the government's anti-smoking message. That will "unquestionably reduce our ability to communicate and reduces the effectiveness of our communication." Claxton Declaration ¶ 16.

b. Under the proposed rule, cigarette advertisements must bear a graphic warning that takes up at least the top 20% of the advertisement. 15 U.S.C. § 1333(b)(2). Although not as onerous as the requirements for cigarette packaging, these restrictions on cigarette advertising will severely impair manufacturers' ability to communicate with adult cigarette consumers. The proposed rule

again seizes the most prominent portion of the advertising space—the top—for the government's message. *See supra* pp. 26–27. And again, FDA's proposed graphic images are plainly designed to evoke feelings of disgust and shame in consumers, and to convey the government's message that people should not smoke cigarettes. *See supra* Section I.B.1. Thus, the proposed rule "would have much the same effect on cigarette advertisements that it has on cigarette packaging: the warnings would either distract consumers from Reynolds's message or repulse consumers and potentially cause them to avoid looking at Reynolds's message at all." Claxton Declaration ¶ 28.

c. The burdens on cigarette packaging and advertising are extremely significant. As FDA concedes, cigarette packages and advertising are very important to manufacturers. *See* 84 Fed. Reg. at 42,759 ("Cigarette packages and advertisements can serve as an important channel for communicating health information to broad audiences that include both smokers and nonsmokers."); *id.* ("The importance of cigarette advertising is reflected in cigarette companies' substantial annual expenditures for cigarette advertising and promotion in the United States, which totaled $1.3 billion in 2017."). And the significance of restrictions on packaging and advertising is all the greater because the ability of cigarette manufacturers to communicate with consumers is already highly limited.

Federal law prohibits cigarette manufacturers from using many forms of communication that advertisers would normally use. For example, federal law prohibits cigarette companies from advertising through television or radio. *See* 15 U.S.C. § 1335. Federal law likewise prohibits cigarette companies from (a) selling or giving away any promotional items (other than matchbooks) that have a brand name, symbol, or colors associated with a cigarette brand, (b) sponsoring "any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event," using a brand name, symbol, or colors associated with a cigarette brand, and (c) giving out free samples. *See* 21 U.S.C. § 387a-1; 21 C.F.R. §§ 1140.16, 1140.34.

Moreover, federal law is not the only source of restrictions on cigarette advertising. In 1998, RAIS and other major cigarette manufacturers settled litigation brought by forty-six states. Under the settlement agreement, known as the Master Settlement Agreement or "MSA," the participating manufacturers agreed to additional restrictions on cigarette advertising, including prohibitions on using billboard and transit advertising, paid product placement, event sponsorships, as well as advertising in sports stadiums and arenas. *See* MSA § III(d), https://tinyurl.com/y6te8olv.

RAIS has also voluntarily adopted its own restrictions to make sure that its advertising focuses on adult tobacco consumers. The vast majority of RAIS marketing takes place through one-on-one, direct interactions with consumers that are third-party verified to be age 21 and older and that have indicated that they want access to tobacco advertising and communications from the Company. In addition, with respect to mass media, RAIS employs strict guidelines to ensure that the audience overwhelmingly consists of adults. For example, RAIS advertises only in print publications where 85% or more of the publication's readership is 18 years of age or older (where

Mediamark Research Inc. ("MRI") print publication 12+ survey data is available) or where the median readership age is at least 23 (where MRI 18+ survey data is available).[5]

RAIS also restricts its marketing in other ways in an effort to avoid content that may have unique appeal to persons under the age of 21. This includes the following:

- No testimonials by sports figures or celebrities or any person with special appeal to persons under 21 years of age;

- No person appearing in any advertising materials shall be under age 25 or be styled to look under age 25;

- Content shall not suggest that use of cigarettes is essential to social prominence, distinction, success, or sexual attraction, nor shall any content picture a person using any products in an exaggerated manner; and

- Content shall not depict persons participating in, or obviously just having participated in, a physical activity requiring stamina or athletic conditioning beyond that of normal recreation.

Taken together, these restrictions mean that RAIS's advertising and communications with adult cigarette consumers are highly restricted. For example, the four most prominent communications channels in traditional media are television, radio, outdoor advertising, and print advertising. Federal law prohibits RAIS from using two of those channels (television and radio), the MSA largely prohibits RAIS from using a third channel (outdoor advertising), and its ability to use the fourth channel (print advertising) is heavily regulated by federal law and limited by our own voluntary policies.

These restrictions make this a far *more* compelling case than *American Beverage Association*, in which the Ninth Circuit invalidated a warning requirement that took up 20% of certain advertisements for sugar-sweetened beverages. *See Am. Beverage Ass'n*, 916 F.3d 749. There, the warning requirement did not apply to many types of marketing communication, including "advertising in or on: periodicals; television; electronic media; [sugar-sweetened beverages] containers or packaging; menus; shelf tags; vehicles used by those in the business of manufacturing, selling, or distributing [sugar-sweetened beverages]; or logos that occupy an area of less than 36 square inches." *Id.* at 753–54. Thus, the government's commandeering of 50% of cigarette packaging and at least 20% of cigarette advertising is a much greater imposition than it would be for manufacturers of most other products, because it takes away a far greater share of the cigarette manufacturers' overall ability to deliver their message. *See Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 564–65 (2001) (noting that, where commercial speakers have "few avenues of communication" with consumers, restrictions on those few avenues can "place a greater, not lesser, burden on [their] speech"); *Linmark Assocs., Inc. v. Twp. of Willingboro*, 431 U.S. 85, 93

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[5] These age-based metrics, which Reynolds originally implemented for cigarette product print advertising as part of a 2004 Settlement Agreement made with the State of California, are consistent with the language of 21 C.F.R. § 1140.32(a)(2)(i) ("For the purposes of this section, an adult publication is a newspaper, magazine, periodical, or other publication: (i) Whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence.").

(1977) (invalidating ban on house "for sale" signs where the alternative avenues of speech existed only "in theory").

d. In contrast to the burdensome graphic-warnings requirement, Congress and FDA have many less-restrictive alternatives for achieving their objectives. For example, they could (a) change the text of the existing warnings, (b) change the size and placement of those warnings, or (c) adopt graphic warnings that have a less-intrusive size and placement or less-provocative content. Congress and FDA could require that each cigarette package include an insert that provides information about various health risks. *See* James F. Thrasher et al., *Cigarette Package Inserts Can Promote Efficacy Beliefs and Sustained Smoking Cessation Attempts: A Longitudinal Assessment of an Innovative Policy in Canada*, 88 Prev. Med. 59 (2016). Congress and FDA could run a public-education campaign about the risks of smoking. *See NIFLA*, 138 S. Ct. at 2376 (holding that a compelled disclosure did not survive even intermediate scrutiny because, among other things, the state could itself "inform low-income women about its services" "with a public-information campaign"). And if Congress and FDA wanted to reduce smoking, they could try giving people accurate information about potentially less-harmful tobacco products and urging them to switch, or giving smokers cessation aids, such as a quitting hotline or free nicotine replacement products. *See* Andrew Whitney, *Michigan Gives Out Free Nicotine Patches, Gum As Part Of Stop Smoking Campaign*, The Heartland Institute (July 24, 2019), https://tinyurl.com/y2atp9dd.

FDA has a constitutional obligation to try all of these less-restrictive alternatives. But two of these options stand out: new textual warnings (without graphic images) and public-education campaigns.

New Textual Warnings. First, adopting new textual warnings without graphic images would almost certainly achieve FDA's informational goal. Since 1965, Congress has required manufacturers to display warnings on all cigarette packages. In part because of those warnings, the public already understands that smoking cigarettes is harmful and knows about the major risks of smoking. *See supra* pp. 14–15. There is no reason to believe that new textual warnings could not be effective.

In addition, the evidence suggests that new textual warnings would be at least as effective as graphic warnings. A recent survey compared the proposed graphic warnings to several different less-restrictive alternatives, such as text-only warnings on the side of the pack. Iyengar Report ¶ 20. That survey found very few statistically significant differences between FDA's proposed warnings and those less-restrictive alternatives regarding the amount of new information conveyed by the warnings and respondents' beliefs about the risks of smoking after viewing the warnings. *Id.* ¶¶ 23–28. For example, for the new-information measurement, there were no statistically significant differences between FDA's proposed warnings and text-only warnings on the side of the pack, and for the health-beliefs measurement, there were no statistically significant differences between FDA's proposed warnings and text-and-graphics warnings on the side of the pack. *See id.* ¶¶ 24, 27. Other studies on less-restrictive alternatives have reached similar conclusions. Klick Report ¶ 7.12; *see also* Glock et al. 2013, at 259 (finding "no difference in risk perception" between groups who saw graphic warnings and textual warnings); Klein et al. 2015, at 182 (finding that "increasing the size of graphic warnings from 20% to 33% of an advertisement's space" had no effect on "smokers' attention" or "repeat views"); Pepper et al. 2013, at 4 (finding that "warnings

with these graphic images did not discourage adolescent males from wanting to smoke more than text-only warnings"). Indeed, new textual warnings might actually be *more* effective than graphic warnings because they do not rely on the type of fear-based appeals that cause some people to "reject[] the message as well as the messenger." Martin Report at 6; *see also supra* Section I.B.6(b).

In the proposed rule, FDA suggests that the Surgeon General's warnings are inadequate because of their "small size," "lack of an image," and "unchanged content." 84 Fed. Reg. at 42,759. But the evidence strongly suggests that any problems with the Surgeon General's warnings stem from the "unchanged content," rather than their size or lack of images. As FDA repeatedly notes, these warnings have not changed in 35 years. *See* 84 Fed Reg. at 42,756, 42,759, 42,760, 42,766. What's more, FDA explains that daily smokers see these warnings "over 5,100 times per year." *Id.* at 42,764, 42,759. And as explained above, the public already knows the information in those warnings. It is no great mystery, therefore, that people often do not read or think about the warnings.

In 2018, RAIS urged FDA to test several less-restrictive alternatives to see whether they would be as effective as graphic warnings. For example, RAIS suggested that FDA "show one group of participants a package with the current Surgeon General's warnings, show 16 groups a package with the new textual warnings, and show 16 more groups a package with the new textual warnings and graphic images." *See* RAIS Comments, Docket No. FDA-2018-N-3552, at 4 (Nov. 16, 2018). This type of study would have "allow[ed] FDA to determine how much the graphic images contribute, if at all, to FDA's stated goal" of conveying information to the public. *Id.* But FDA flatly refused to test this—or any other—less-restrictive alternative. Given FDA's refusal to test these alternatives, FDA has no basis whatsoever to conclude that any "new information" conveyed by, or any "self-reported learning" caused by, the proposed warning is attributable to the graphic images, rather than the textual warning statements.

Public-Education Campaign. There is also strong evidence that an FDA-run public-education campaign would be significantly more effective than the proposed graphic warnings.

Over the past several decades, FDA has run multiple public-education campaigns to educate the public about the risks of smoking cigarettes. Between 2009 and 2014, FDA spent more than $500 million on such campaigns. U.S. Gov't Accountability Office, No. 14-561, *Most FDA Spending Funded Public Education, Regulatory Science, and Compliance and Enforcement Activities* at 16–17 (June 2014), https://tinyurl.com/y93gktex. And since 2014, FDA has run several different campaigns, including *The Real Cost*, *Fresh Empire*, *This Free Life*, and *Every Try Counts*.

These campaigns have several advantages over graphic warnings. These campaigns can use many different communication channels, such as television, radio, websites, and social media, that allow the speaker to convey more information than FDA can convey through graphic warnings. Steenkamp Report § 4.4. These campaigns can also be changed more quickly than graphic warnings, which allows the speaker to convey more current information. Klick Report ¶ 5.14. And these campaigns can target particular groups by using different messages and different communication channels, rather than using a "one-size-fits-all message" like graphic warnings. Steenkamp Report at § 3.1.

FDA has conceded that public-education campaigns have many of these benefits. For example, in the context of its ongoing *The Real Cost* campaign regarding the dangers of e-cigarettes, FDA has boasted about its ability to "ensure [that its] messages are reaching the intended youth audience" by, among other methods, (1) running ads "on age-verified digital platforms such as YouTube, Spotify, Pandora, Facebook and Instagram," (2) "using location-targeted advertising around high schools nationwide," and (3) placing e-cigarette prevention content on educational platforms that are typically accessed by students during the school day." FDA News Release (Sept. 18, 2018), https://tinyurl.com/y2adoe6w; *see also* FDA News Release (July 22, 2019), https://tinyurl.com/yxnkj52k (explaining that the *Real Cost* campaign's new ads would "run on television networks such as TeenNick, CW, ESPN and MTV, as well as music streaming sites, social media networks and other teen-focused media channels"); *id.* (explaining that the *Real Cost* campaign "has generated nearly 2 billion teen views in 9.5 months," and has received "more than 578,000 likes, 89,000 shares, and 31,000 comments" on social media platforms).

FDA has also suggested that public-education campaigns can reduce smoking. Indeed, the same week that FDA issued the proposed rule, FDA touted the *Real Cost* campaign as "highly successful" and as "yielding tremendous results." Norman E. Sharpless, *Press Announcement* (Aug. 20, 2019), https://tinyurl.com/y3kmouoa. Specifically, FDA alleged that the *Real Cost* campaign had "prevented up to 587,000 youth nationwide from initiating smoking between the campaign's launch in February 2014 and November 2016, half of whom might have gone on to become established smokers." *Id.*; *see also* Duke et al. 2019. And in late September 2019, FDA boasted about a "series of groundbreaking public education initiatives to prevent young people from ever starting to use tobacco and to help addicted smokers quit." FDA's Center for Tobacco Products, *Prevention Through Public Education* (Sept. 24, 2019), https://tinyurl.com/y6c6veez.

In sum, the evidence strongly suggests that these less-restrictive alternatives would achieve FDA's informational objective. For the past several decades, the government has used a combination of textual warnings (without graphic images) and public-education campaigns to tell the public about the major risks of smoking, such as lung cancer. *See supra* Section I.B.6(a). Because of those efforts, the public *universally understands* those risks, and actually *overestimates* many of them. *See id.* There is no reason to believe that these less-restrictive alternatives would be any less effective here.

e. The proposed rule does not meaningfully discuss the burdens that graphic warnings place on manufacturers or FDA's less-restrictive alternatives. Instead, FDA cites *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012), for the proposition that the Tobacco Control Act's graphic-warnings requirement is "not unduly burdensome because a manufacturer has the ability to convey other information of its choosing in the remaining space available." 84 Fed. Reg. at 42,778 (citing *Disc. Tobacco*, 674 F.3d at 530–31). But FDA fails to acknowledge that it cites the *dissenting opinion* for that proposition.

FDA likewise fails to acknowledge that it has the burden of proving that less-restrictive alternatives are not sufficiently effective. *NIFLA*, 138 S. Ct. at 2376 ("California argues that it has already tried an advertising campaign, and that many women who are eligible for publicly-funded healthcare have not enrolled. But California has identified no evidence to that effect."); *Philip Morris*, 566 F.3d at 1143 ("Although the standard for assessing burdens on commercial speech has

varied, the Supreme Court's bottom line is clear: the government must affirmatively demonstrate its means are 'narrowly tailored' to achieve a substantial government goal." (citations omitted)). And FDA has not even tried to carry that burden. FDA has not demonstrated that new textual warnings would be insufficient to educate the public—indeed, FDA refused to test that less-restrictive alternative when it had the chance. FDA has not shown that it even *tried* running a public-education campaign about the risks identified in the proposed warnings, much less that such a campaign would be unsuccessful. That is not enough to satisfy *Zauderer*.

C.   **The *Central Hudson* standard likewise does not save the graphic-warnings requirement or the proposed rule.**

FDA also suggests that the proposed rule "would pass a First Amendment analysis under … *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980)." 84 Fed. Reg. at 42,757. Under *Central Hudson*, courts must analyze four factors to determine whether a restriction on commercial speech violates the First Amendment: (1) whether the speech "concern[s] lawful activity" and is not "misleading"; (2) "whether the asserted governmental interest is substantial"; (3) "whether the regulation directly advances the governmental interest asserted"; and (4) "whether it is not more extensive than is necessary to serve that interest." *Cent. Hudson*, 447 U.S. at 566. But the *Central Hudson* standard does not apply to the proposed rule. And even if it did, the proposed rule would not satisfy it.

1. To begin, the *Central Hudson* test is not applicable here. Strict scrutiny, rather than *Central Hudson*, governs situations, like this one, where the government compels commercial actors to disseminate non-factual, controversial policy statements. *See, e.g.*, *Brown v. Entm't Merchants Ass'n*, 564 U.S. 786, 799 (2011) (applying strict scrutiny to law requiring warning label for "violent" video games); *Pac. Gas*, 475 U.S. at 17-18 (plurality op.) (strict scrutiny applied to requirement that utility "use its property—the billing envelopes—to distribute the [policy] message of another"); *id*. at 21 (Burger, C.J., concurring) ("To compel [utility] to mail messages for others cannot be distinguished from compelling it to carry the messages of others on its trucks, its buildings, or other property used in the conduct of its business"); *Entm't Software*, 469 F.3d at 652 (7th Cir. 2006) (applying strict scrutiny to law requiring warning label for "sexually explicit" video game).

It is no answer to observe that *cigarette packaging* is commercial speech. The key point is that the *compelled speech* here is not commercial speech. Instead, the government seeks to compel cigarette manufacturers to disseminate the government's policy view that consumers should not use lawful tobacco products. For example, it is apparent that strict scrutiny would apply if the government forced cigarette manufacturers to "urge [their] customers to vote for a particular slate of legislative candidates," *Pacific Gas*, 475 U.S. at 15–16, even if the message were placed on cigarette packaging.

2. In any event, even if *Central Hudson* review were appropriate, the proposed rule would be unconstitutional, for the same reasons discussed in the analysis of *Zauderer* above. First, the proposed rule's purely informational purpose is not a "substantial interest," *see Cent. Hudson*, 447 U.S. at 564, under the same analysis as above.

Second, the proposed rule does not "directly" or "materially" advance the government's interest. *See id.* Under this prong, FDA would need to show that the proposed graphic-warnings rule directly advanced the government's interest, and that the rule did so "to a material degree." *Edenfield v. Fane*, 507 U.S. 761, 771 (1993). And as explained above, the public already understands that smoking cigarettes can cause serious diseases and harm one's health. So FDA cannot possibly demonstrate that the proposed rule would directly and materially advance its purported interest in increasing consumer understanding. Moreover, FDA has not even tried to demonstrate that the proposed rule would reduce smoking. And it could not have made such a showing even if it had tried. *See R.J. Reynolds*, 696 F.3d at 1219 ("FDA has not provided a shred of evidence—much less the 'substantial evidence' required by the APA—showing that the graphic warnings will 'directly advance' its interest in reducing the number of Americans who smoke.").

Third, the proposed rule is "more extensive than is necessary to serve [the government's] interest." *Cent. Hudson*, 447 U.S. at 566. Under this prong, "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371 (2002). As explained above, Congress could have made the Tobacco Control Act less restrictive, and even within the Act's framework, FDA could achieve its objectives using less-restrictive means.

* * *

To sum up, the rule fails under any First Amendment standard. This is no surprise, because compelling advocacy in a paternalistic effort to remove a disfavored product from the market is invalid—regardless of the standard of review. Although FDA is unwilling to admit it, the whole point of the proposed rule is to use fear and shame to get people to stop smoking cigarettes by turning manufacturers' packaging into mini-billboards for the government's anti-smoking message. That violates the First Amendment: FDA cannot compel speech "to remove a popular but disfavored product from the marketplace." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 577–78 (2011).

FDA "may be displeased" that people still smoke cigarettes. *Id*. at 578. But FDA "can express that view through its own speech." *Id*. What FDA cannot do is compel cigarette manufacturers to campaign against themselves in an attempt "to tilt public debate in a preferred direction." *Id*. at 578–79 (citation and quotation marks omitted). "The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented." *Id*. at 579 (quotation marks omitted); *Lorillard* , 533 U.S. at 571 ("The First Amendment also constrains state efforts to limit advertising of tobacco products, because so long as the sale and use of tobacco is lawful for adults, the tobacco industry has a protected interest in communicating information about its products and adult customers have an interest in receiving that information.").

In short, the rule is fundamentally misconceived and incompatible with the First Amendment. FDA should withdraw the proposed rule and refuse to enforce the Tobacco Control Act's unconstitutional graphic-warnings provision.

II. THE TOBACCO CONTROL ACT DOES NOT AUTHORIZE FDA'S PROPOSED CHANGES TO THE STATUTORILY MANDATED TEXTUAL WARNINGS.

In addition to requiring graphic warnings, the proposed rule replaces all but two of the textual warning statements prescribed by the Tobacco Control Act, and increases the number of the warnings from nine to thirteen. 84 Fed. Reg. at. 42,772–77. FDA lacks the statutory authority to alter the Act's textual warning statements in this manner. To begin, the statute does not authorize FDA to change the *content* of the Act's warning statements at all; at a minimum, it does not authorize FDA to change the content of those warnings *without having implemented them first.* In addition, the statute precludes FDA from increasing the number of the warnings, as the proposed rule would do.

A. FDA lacks authority to alter the Tobacco Control Act's warning statements.

1. The Tobacco Control Act amended the Federal Cigarette Labeling and Advertising Act ("Labeling Act") to require all cigarette packages and advertisements to bear one of nine "label statements" warning of the health risks of smoking cigarettes. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 201(a), 123 Stat. 1,776 (2009) ("TCA"). Congress also instructed FDA to adopt graphic warnings to "accompany the [specified] label statements." *Id.* at 201(d). In adopting the graphic warnings, FDA may "adjust the type size, text, and format of the label statements … so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area." *Id.* And FDA may further "adjust the format, type size, color graphics and text of any of the label requirements" to promote greater public understanding of the risks of tobacco products. TCA § 202(b).

FDA claims that this latter provision, Section 4(d)[2][6] of the Labeling Act, gives it the authority to alter the nine statutorily mandated textual warning statements. 84 Fed. Reg. at 42,772. This is wrong because, for several reasons, the word "text" in Section 4(d)[2] refers only to formatting-type specifications, not to substantive changes in the content of the warnings. *See, e.g.*, Webster's Third New International Dictionary 2365 (1993) (noting that "text" can refer to the "words *and form* of a literary work" (emphasis added)). First, the word "text" appears in Section 4(d)[2] as part of a list of typographical considerations. Under the well-known *noscitur a sociis* canon, this strongly suggests that the word "text" should also be understood to refer to typography. *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004) (explaining that "[t]he canon of statutory construction, *noscitur a sociis*, i.e., a word is known by the company it keeps … is often wisely applied where a word is capable of many meanings in order to avoid giving unintended breadth to the Acts of Congress." (quotation marks omitted)). Notably, the word "text" also appears in a list of typographical considerations in Section 4(d)[1]. And in that section, the word unmistakably carries a typographical connotation because Section 4(d)[1] gives the Secretary the power to adjust the text of the label statements *only* to ensure that they "are clear, conspicuous, legible, and appear within the specified area"—objectives that could never be accomplished by changing the *substantive* content of the warning statement. The word "text" presumptively means the same thing

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[6] Due to an apparent scrivener's error, the Tobacco Control Act added two subsections (d) to section 4 of the Labeling Act. *See* TCA §§ 201(a), 202(b). These comments will refer to them as Section 4(d)[1] and Section 4(d)[2], based on the order in which they appear.

in both sections, *see, e.g.*, *Sullivan v. Stroop*, 496 U.S. 478, 484 (1990), so this is yet another reason to interpret the word as referring only to formatting-type specifications in Section 4(d)[2].

In contrast, the statute consistently uses the terms "labels" or "label statements"—rather than the word "text"— to describe the substantive content of the textual warnings. *See, e.g.*, 15 U.S.C. § 1333(a)(1), (2), (c)(1), (2). In addition, Section 4(d)(2) uses the term "adjust," which is much more naturally read to refer to typographical changes than to substantive changes. For example, an editor who wants a journalist to substantively change a draft of an article would not ask the journalist to "adjust the text" of the article—she would ask the journalist to *revise,* or *edit*, the text of the article.

2. Moreover, even if Section 4(d)[2] *did* give FDA the authority to alter the substantive content of the label statements, that authority is premised on the assumption that the Act's mandated warning labels *have already been implemented*. This is also true for several reasons. To begin, Section 4(d)[1] expressly provides that graphic warnings should "accompany" the subsection (a)(1) label statements. And Section 4(d)[2]'s grant of authority to adjust the "graphics" as well as the text of the labels presupposes that FDA will exercise this authority only after having implemented an original set of graphic warnings. In addition, FDA's preferred reading of Section 4(d)[2] would render part of Section 4(d)[1] superfluous. Section 4(d)[1] provides a narrower authorization to adjust the text of the label statements to ensure that they are clear, conspicuous, and legible. If FDA could rely on Section 4(d)[2]'s broader authority to change "the text of any of the label requirements" when issuing a graphic-warnings rule, then the Agency would have no reason to invoke Section 4(d)[1]'s narrower authority. That would violate the Supreme Court's repeated instruction that a "statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *See Corley v. United States*, 556 U.S. 303, 314 (2009).

Finally, Section 4(d)[2] itself ensures that any changes made to the statutory label statements are based on the Agency's finding about the statutory labels' *relative* effectiveness compared to other potential labels. Specifically, Section 4(d)[2] authorizes "change" in the warning statements *if* the Secretary finds that the change would "promote *greater* understanding" of tobacco-product risks. (Emphasis added). This reveals one of Congress's motivating interests in authorizing FDA to make changes to the textual warnings: preventing label warnings from becoming stale. And indeed, FDA acknowledges that the warning statements in use today are inadequate because they often go unnoticed. 84 Fed. Reg. at 42,755. This emphasis on *relative* effectiveness further demonstrates that Congress fully intended that the statutory labels would apply *as set forth in the statute* and could be changed only based on *evidence that they could be improved*.

Obviously, FDA was in no position to make such a finding here because it never implemented the statutory warnings. But even if it were entitled to make a finding of relative effectiveness *without* having implemented the statutory warnings, the finding it has made is faulty by its own standard. FDA asserts that the revised textual warnings will promote greater public understanding of the risks associated with cigarette smoking. 84 Fed. Reg. at 42,773. But the proposed rule acknowledges that increasing public understanding is a two-step process. First, an individual must "notice the warning and must be made aware of the information contained in that warning"; second, having noticed the warning, the individual must "mentally store[] the

information" and "give[] meaning to [it]," so it can be remembered later. *Id.* at 42,762, 42764. This is a commonsensical observation: for a warning to increase public understanding, the public must both *notice* the content of the message and then *process* the information in a way that allows it to be recalled later. *Id.* But the "empirical results" on which FDA relies, 84 Fed. Reg. at 42,772–73, can support at most only the first of those two steps.

To determine whether to change the textual warning statements, FDA conducted a consumer research study. As the proposed rule concedes, however, this study concluded *only* that people would be more likely to notice the modified warning statements; it did *not* conclude that people would be more likely to recall the information later (as would be required, under FDA's own analysis, to demonstrate greater public understanding). Specifically, the study purportedly found that the revised warning statements in the proposed rule "demonstrated statistically significant higher levels of both 'new information' and 'self-reported learning' when compared to a TCA statement." *Id.* at 42,768. But that is only the "*first step* in promoting public understanding of health risks." *Id.* at 42,769 (emphasis added). As explained above, there is a *second step*—namely, finding that the public would be more likely to recall the information later.

FDA's consumer research study did attempt to test whether the revised warning statements led to greater understanding of the health risks identified in the warnings. But the results were poor: of the thirteen proposed warning statements, only six demonstrated a statistically significant improvement over the Tobacco Control Act's warnings. Study 1 Results Report at 3-16 to 3-17. Given these poor results, FDA effectively wrote off the test, explaining that people's "health beliefs" were "unlikely to change with a single brief exposure to the text-only statements—as was provided in this first quantitative consumer research study." *Id.* at 42,769. Instead of designing a study that gave people more than a "single brief exposure to the text-only statements," however, FDA simply assumed that people's "health beliefs" were "not … predictive of improved understanding." *Id.* Because FDA did not conclude that the revised warnings actually improved the public's understanding of the risks of smoking, the Agency had no evidence on which to make the finding required by the Tobacco Control Act.

B. FDA also lacks authority to change the number of textual warnings.

In addition to eliminating most of the Tobacco Control Act's warnings, FDA has changed their total number from nine to thirteen. There is no statutory authority for this change. As noted above, Section 4(d)[2] empowers FDA to "adjust the format, type size, color graphics, and text of any of the label requirements." Nothing in the statute, however, allows FDA to create *additional* label requirements. If Congress had intended to authorize FDA to create additional textual labels for cigarettes, it would have done so expressly, as it has done elsewhere in the U.S. Code. *See, e.g.*, 21 U.S.C. § 343(q)(2)(A) (providing that, if FDA determines that "a nutrient, other than [those listed in the code], should be included [on food labels] for purposes of providing information … to assist consumers … [it] may by regulation require that information relating to such additional nutrient be included"). In other words, whatever FDA's authority to alter the Act's warnings, it has no authority to impose *additional* warnings, as the proposed rule would do.

III. THE PROPOSED RULE DOES NOT COMPLY WITH THE ADMINISTRATIVE PROCEDURE ACT.

The proposed rule also violates the Administrative Procedure Act in several respects. First, FDA improperly relied on an inadequate cost-benefit analysis (which, among other problems, completely fails to quantify the rule's purported benefits). Second, FDA failed to articulate a rational justification for the rule. Third, FDA failed to consider reasonable alternatives. And finally, FDA has failed to give the public a meaningful opportunity to comment, and instead has withheld information from the public at every turn.

Some of these errors may have resulted from a court order requiring FDA to release its proposed rule far earlier than FDA had hoped. Memorandum and Order at 5, *American Academy of Pediatrics et al. v. FDA*, No. 1:16-cv-11985-IT (Mar. 5, 2019). The same court order also requires FDA to publish its final rule on an expedited timeline; as a result, FDA will not have the opportunity to meaningfully respond to the comments it receives.

A. The proposed rule's cost-benefit analysis is irrational.

Where an agency "decides to rely on a cost-benefit analysis as part of its rulemaking," that analysis must itself be reasonable. *National Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012) (noting that the court would not "tolerate rules based on arbitrary and capricious cost-benefit analyses" (quotation marks omitted)); *Idaho Conservation League v. Wheeler*, 940 F.3d 494, 507 (D.C. Cir. 2019) ("[W]hen an agency decides to rely on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable." (quotation marks omitted)); *see also, e.g., Business Roundtable v. S.E.C.*, 647 F.3d 1144, 1148 (D.C. Cir. 2011) (noting that an agency had acted arbitrarily and capriciously in failing "adequately to assess the economic effects of a new rule"). The purported cost-benefit analysis accompanying the proposed rule does not come close to satisfying this requirement; to the contrary, it is fundamentally inadequate in several respects.

The failures of this cost-benefit analysis are especially notable in light of FDA's experience with the original graphic-warnings rule. In the regulatory impact analysis that accompanied that rule, FDA attempted to quantify the reduction in smoking that the rule would supposedly produce. As the D.C. Circuit noted, however, the result of that analysis was that the reduction would be *de minimis*, and could not be statistically distinguished from zero. *R.J. Reynolds*, 696 F.3d at 1219–20. The agency's cost-benefit analysis, in short, did not amount to even "a shred of evidence— much less the 'substantial evidence' required by the APA—showing that the graphic warnings will 'directly advance' its interest in reducing the number of Americans who smoke." *Id.* at 1219. One might have expected that, mindful of this rebuke, the Agency would be especially careful this time around to provide a rigorous and thorough analysis quantifying the proposed rule's purported benefits. Remarkably, FDA did precisely the opposite and *declined to attempt to quantify those benefits at all*. It is hard to interpret this decision as anything other than a tacit admission that those benefits simply do not exist.

1. At a minimum, a cost-benefit analysis must quantify both the costs and the benefits of the proposed regulation. Klick Report ¶ 8.5. Notably, the preliminary regulatory impact analysis that accompanies the proposed rule fails to meet even that low bar. Instead, it expressly forgoes

any effort to quantify the proposed rule's benefits. It acknowledges that "there is a high level of uncertainty around quantitative economic benefits" and therefore chooses to "describe them qualitatively." PRIA at 2. As a result, no direct comparison is possible between the rule's benefits and its costs. Instead, FDA is forced to rely on a "break-even calculation," which concludes that the rule will be beneficial on net "[i]f the information provided by the cigarette health warning on each cigarette package were valued at about $0.01." *Id.* at 37–38. This is not helpful in evaluating the rule, as FDA provides no reason to believe that the informational benefit *is* worth $0.01 or more per pack. Indeed, as Professor Klick shows, the per-pack benefits could be less than zero even before the costs of the regulation are taken into account. Klick Report ¶ 8.6. In short, FDA's cost-benefit analysis says *nothing* about whether the rule's benefits exceed its costs, and indeed about whether the benefits exist at all—let alone whether they could possibly be sufficient to satisfy the demands of the First Amendment.

Break-even analyses of this sort have been criticized as an unproven tool which may not improve the rationality of regulatory analyses. *Id.* ¶ 8.7. A key weakness of break-even analyses, which is on full display here, is that they are overly dependent on framing effects. *Id.* By choosing to frame the break-even benefit on a per-pack basis, FDA was able to claim that the threshold for the rule to become beneficial was seemingly low—just $0.01 per pack. But if FDA had framed the break-even benefit on a per-smoker basis, the required benefit would be much larger—perhaps $400 per smoker. *Id.* That threshold might appear much harder to satisfy, even though it is simply another way of describing the same required aggregate benefit. This further illustrates the irrationality of FDA's approach.

FDA's failure to quantify the rule's benefits is particularly egregious in light of the fact that the benefits are almost certainly small or nonexistent. The only interest FDA asserts is in promoting greater public understanding of the dangers of smoking. But as explained above, the rule will not meaningfully contribute to that goal, as the dangers of smoking are already widely understood. *See supra* Section I.B.6(a). And even if the rule did impart some information to consumers, FDA would have no basis for asserting that the information would be valuable. *See supra* Section I.B.6(b). Ordinarily, in economic analysis, the value of information is estimated by measuring the effect of that information on behavior. Klick Report ¶ 8.5. Here, however, FDA does not claim that the warnings would cause any change in behavior (and, as discussed above, the warnings in fact would not cause any reduction in smoking). As such, it is "difficult to understand" how the information conveyed by the warnings could be valuable. *Id.* Alternatively, FDA might have attempted to estimate the value of the information based on willingness to pay. But those estimates would likely have been negligible because the information is freely and easily accessible from a variety of sources, including government websites. *Id.*

Notably, in other contexts, FDA is quite willing to quantify the benefits of its programs. For example, it recently asserted that its *Real Cost* campaign had "prevented up to 587,000 youth nationwide from initiating smoking," and would purportedly "save more than $53 billion for youth, their families and society at large by reducing smoking-related costs like early loss of life, costly medical care, lost wages, lower productivity and increased disability." Norman E. Sharpless, *Press Announcement* (Aug. 20, 2019), https://tinyurl.com/y3kmouoa.

2. Moreover, while FDA *does* purport to quantify the rule's costs, it underestimates those costs by entirely overlooking several categories of costs. First, FDA fails to take into account the

cost of RAIS's lost ability to use its packaging to communicate with consumers. FDA recognizes that requiring manufacturers to devote 20% of their advertising space to graphic warnings would impose costs. PRIA at 34. But FDA fails to recognize that requiring manufacturers to devote 50% of their packaging space to graphic warnings would also impose costs. *See* Klick Report ¶ 8.8. FDA fails to account for those costs, even though FDA acknowledges that advertising is very important to cigarette companies. *See* 84 Fed. Reg. at 42,759. In addition, FDA ignores the psychic costs to consumers who prefer the look of the original pack. Klick Report ¶¶ 8.9–8.10.

In sum, the cost-benefit analysis supporting the proposed rule is both inadequate and irrational. FDA's reliance on it is arbitrary and capricious under the APA.

B. FDA has failed to articulate a rational explanation for the proposed rule.

Under the APA, a rule is arbitrary and capricious if the agency fails to "articulate a satisfactory explanation for [the rule] including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983) (quotation marks omitted). Here, FDA has not articulated a rational justification for the proposed rule.

1. FDA claims that the proposed rule will increase consumer understanding of the risks of smoking. But as explained above, the public already overwhelmingly understands that smoking cigarettes can harm one's health, and in any event the proposed warnings would not affect the public's assessment of the hazards of smoking. FDA fails to account for those facts.

More generally, FDA relies on studies that are deeply flawed. Klick Report ¶ 8.4. For example, its first quantitative study did not consider a representative sample of the U.S. population. The Office of Management and Budget granted only a limited approval of that study and noted that, "[d]ue to the study design, convenience sampling methodology, and methods of analyses— significant limitations exist with regard to the generalizability of results from this study." OMB, *Notice of Office of Management and Budget Action, Experimental Study on Warning Statements for Cigarette Graphic Health Warnings, Ref. No. 201708-0910-011* (Jan. 29, 2018), https://tinyurl.com/ybwk7ptv. "Because of these limitations, the relationship between treatment and outcomes [that FDA] find[s] in [its] study *may not generalize to the broader U.S. population.*" *Id.* (emphasis added). Thus, FDA had to "confirm[] that all such limitations inherent in the study design and methodology will be communicated in all reports, presentations, and policy documents." *Id.* Accordingly, FDA now acknowledges that the survey for this study "used a convenience sample rather than a probability sample, and the results are not nationally representative." Study 1 Results Report at 4-4.

The second quantitative study also suffered from serious problems. Klick Report ¶ 8.4. As RAIS explained in its comments, this study (1) had a small sample size, (2) suffered from selection bias, (3) asked questions that created a serious risk of bias, (4) failed to adequately mimic real-world conditions, (5) lacked meaningful pretesting, and (6) failed to correct for social-desirability bias. RAIS Comment, Docket No. FDA-2018-N-3552 (Nov. 16, 2018); *see* Robert Hornik, *Proposal for an Administrative Supplement to a Research Grant from the National Institutes of Health* (Oct. 21, 2011) (attached as Exhibit M) ("Most current research supporting GWL choice involved single exposures to graphics and evaluation of responses. In contrast, most real life

exposure to the graphic labels will take place repeatedly, as smokers open packs of cigarettes every day, or non-smokers see the strong graphics repeatedly as they pass convenience stores daily which feature poster ads for a tobacco brand. Repeated exposures may produce quite different effects than single exposures[.]"). FDA has failed to meaningfully address those comments. *International Fabricare Institute v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992) (noting that the APA requires agencies to "give reasoned responses to all significant comments in a rulemaking proceeding"). Indeed, it has admitted that the study sample was "not truly nationally representative." FDA, *Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Cigarette Warnings*, 83 Fed. Reg. 65,685, 65,687 (Dec. 21, 2018); *see also* Study 2 Results Report at 4-2 ("[T]he survey used a convenience sample rather than a probability sample, and the results are not nationally representative.").

Moreover, neither study had been peer-reviewed when FDA issued the proposed rule. 84 Fed. Reg. at 42,768 n.6 (first quantitative study); *id*. at 42,772 n.9 (second quantitative study); *see also* Klick Report ¶ 8.4. Both studies therefore state that they have been "distributed solely for the purpose of the pre-dissemination peer review under applicable information quality guidelines," that they have "not been formally disseminated by FDA," and that they do "not represent and should not be construed to represent any agency determination or policy." Study 1 Results Report; Study 2 Results Report. Expecting the public to meaningfully comment on a study that has not been peer-reviewed and has "not been formally disseminated by FDA" is arbitrary and capricious. More fundamentally, resting a massively burdensome speech restriction on a study that does not represent an agency determination is quintessential arbitrary and capricious action.

The studies also suffer from another crucial defect: they make no attempt to study any outcomes related to actual smoking behavior, and instead focus entirely on self-reported answers to questions such as whether the graphic warnings provided new information and whether participants learned something from the warnings. Klick Report ¶ 8.1. As Professor Klick explains, "FDA provides no foundation for determining whether these measures reflect what is necessary to make adequately informed decisions with respect to smoking." *Id.*

And even if the studies were methodologically sound, they would not provide a secure foundation for FDA's conclusions because "many of the proposed warnings do not fare particularly well measured by the FDA's own metrics." *Id.* ¶ 8.2. The bladder cancer graphic health warning, for example, did not significantly affect how much respondents thought about the risk, their health beliefs about the risks, or the degree to which people found the warning to be informative; indeed, the warning actually reduced respondents' ratings of the believability and factuality of the risk. *Id.* More generally, in the second quantitative study, "many of the tested warnings … were associated with reduced perception of the factuality of the risk, including both blindness warnings, the diabetes warning, and the erectile dysfunction warning." *Id.* In short, even by FDA's metrics, the warnings "do not appear to consistently provide believable information," and indeed may even be viewed "as less factual than non-graphic warnings." *Id.* ¶ 8.3. In other words, the warnings "provide very little, if any, value"—and indeed "may actually provide negative benefits even before the production and administration costs are considered." *Id.* As such, it is arbitrary and capricious to suggest that these studies support the informational rationale for the proposed rule.

2. Similarly, FDA has failed to articulate a rational justification for its decision to change the textual warnings. As discussed above, FDA failed to adduce any evidence that the information will actually be retained by consumers, leading to greater public understanding of the relevant risks. Moreover, FDA's approach here is arbitrary because it conflicts with FDA's own previous approach to changing textual warnings. In 2011, RAIS submitted a citizen petition requesting that FDA change a misleading warning label for smokeless tobacco products. R.J. Reynolds Citizen Petition, Docket No. FDA-2011-P-0573 (Jul. 28, 2011). The petition included ample evidence demonstrating that the warning—which stated that smokeless tobacco products were "not a safe alternative to cigarettes"—was misleading to the public because it created the impression that smokeless tobacco products were *as* dangerous as cigarettes. The evidence presented by RAIS made a compelling case that changing the text of the warning would promote greater public understanding—certainly a more compelling case than FDA has made here. And nevertheless FDA declined to change the warning. Letter from Mitchell Zeller to Martin L. Holton, RE: Docket No. FDA-2011-P-0573-0001/CP (May 11, 2015). Here, by contrast, FDA has decided to change the textual warnings based on far weaker evidence. This decision is arbitrary and capricious both because FDA has failed to treat like cases alike, and because FDA has failed to explain (or even acknowledge) the change in its approach. *See, e.g.*, *Cty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1022 (D.C. Cir. 1999) ("A long line of precedent has established that an agency action is arbitrary when the agency offers insufficient reasons for treating similar situations differently." (quotation marks and alterations omitted)); *Kaiser Found. Hosps. v. Sebelius*, 708 F.3d 226, 233 (D.C. Cir. 2013) (holding that "the Secretary has acted arbitrarily in treating similarly situated parties differently"); *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125–26 (2016) (explaining that agencies must "provide a reasoned explanation for [a] change" in policy, and that "an unexplained inconsistency in agency policy is a reason for holding an interpretation to be an arbitrary and capricious change from agency practice" (quotation marks and alterations omitted)).

C.   FDA has failed to consider reasonable alternatives.

Under the APA, a rule is arbitrary and capricious if the agency ignores alternative regulatory approaches that were "neither frivolous nor out of bounds." *Chamber of Commerce v. SEC*, 412 F.3d 133, 144–45 (D.C. Cir. 2005); *see also Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 817 (D.C. Cir. 1983) (explaining that a rule is arbitrary and capricious if it fails to consider a reasonable range of alternative actions). The First Amendment imposes a similar requirement. As explained above, under any standard of review—strict scrutiny, *Zauderer*, or *Central Hudson*—FDA had an obligation to consider whether it could achieve its aims in a less-burdensome way. Thus, "[a]lthough the standard for assessing burdens on commercial speech has varied, the Supreme Court's bottom line is clear: the government must affirmatively demonstrate its means are 'narrowly tailored' to achieve a substantial government goal." *See Philip Morris*, 566 F.3d at 1143 (citations omitted). As noted above, FDA has an independent obligation to act constitutionally, regardless of statutory commands; and in any event, there were alternatives available to FDA that would be consistent with the statutory requirements (such as less-provocative warnings). *See supra* pp. 2–3.

Here, FDA failed to sufficiently consider less-restrictive alternatives to the proposed graphic-warnings rule, even though it was constitutionally and statutorily required to do so. For example, FDA tested whether the new graphic warnings did a better job of educating the public than the current Surgeon General's warnings, but FDA did not test whether new text-only warnings

would have the same effect. In other words, FDA did not attempt to isolate the effects of the graphics, separate from the effects of the new textual warning statements. It's possible—indeed, likely—that the purported improvements in "new information" and "self-reported learning" are attributable entirely to the latter. More generally, in earlier comments, RAIS proposed several less-restrictive alternatives that FDA could—and should—have considered. For example, RAIS suggested that FDA alter the size and placement of the current warnings. Yet FDA failed to consider any of these suggestions. *See* RAIS Comments, Docket No. FDA-2018-N-3552, at 4 (Nov. 16, 2018). This failure is particularly consequential given that it is likely that alternative approaches could achieve FDA's information goals while avoiding the costs of the proposed rule. *See* Klick Report ¶ 8.11.

Instead, FDA considered only three alternative approaches, which involved only changes in timing or in the number of required warnings. PRIA at 43–54. And notably, even as to those alternatives, FDA provided no rational explanation as to why it had not adopted them. Indeed, it could not do so, given its total failure to quantify the benefits of the rule. *See* Klick Report ¶¶ 8.7 n.139, 8.11. For example, FDA considered the alternative of requiring only nine warnings, instead of thirteen. PRIA at 51–54. Unsurprisingly, FDA found that this rule would be less costly than the proposed rule. *Id.* at 54. And FDA did not (and could not) demonstrate that the greater cost of the proposed rule is offset by any greater benefit. Accordingly, it has given no rational reason—indeed, it has not given any reason at all—for choosing thirteen labels instead of nine.

D.   FDA has failed to provide a meaningful opportunity to comment.

FDA is obligated to "provide the public with a meaningful opportunity to comment on" new regulations prior to their publication. *Hall v. EPA*, 273 F.3d 1146, 1162-–63 (9th Cir. 2001) (quotation marks omitted) (citing 5 U.S.C. § 553(b)(3)); *Owner-Operator Ind. Drivers Ass'n v. Federal Motor Carrier Safety Administration*, 494 F.3d 188, 201 (D.C. Cir. 2007) ("failure to provide an opportunity for comment on" key statistical model relied on by agency "constitutes a violation of the APA's notice-and-comment requirements"). Here, FDA has failed to provide a meaningful opportunity to comment; to the contrary, it has tried to hide information from the public at every turn.

For example, FDA issued notices about each of its quantitative studies. But those notices provided precious little information about the studies' methodology. Indeed, the notice concerning the second quantitative study failed to include even the text and graphics that make up the warnings themselves—the very object of the study. *See* FDA, *Experimental Study on Warning Statements for Cigarette Graphic Health Warnings*, 82 Fed. Reg. 15,359 (Mar. 28, 2017); FDA, *Experimental Study of Cigarette Warnings*, 83 Fed. Reg. 48,625 (Sept. 26, 2018). And while the Agency has now released reports about those two studies, it still has yet to release the full underlying data, including data about participants' baseline knowledge about the negative health consequences of cigarettes smoking. *See* 84 Fed. Reg. at 42,771 (mentioning that FDA gathered this data, but not reporting the results).

FDA has been even less forthcoming with respect to the two qualitative studies it conducted. Not only has it not released the underlying data for those studies—it has not even provided study reports. Instead, the only publicly available information about these studies consists of the short descriptions that are provided in the proposed rule itself. 84 Fed. Reg. at 42,767,

42,771. Those cursory descriptions are not remotely adequate to allow the public to evaluate the studies themselves, or the role they played in FDA's analysis.

More broadly, FDA has failed to disclose a wide range of information regarding the deliberative process that culminated in the proposed rule. In 2017, RAIS's outside counsel submitted a broad Freedom of Information Request seeking several categories of documents pertaining to FDA's research into graphic and textual warnings. Letter from Caitlyn J. Ozier, to FDA (Jun. 14, 2017) (attached as Exhibit P). FDA has yet to produce *any* documents in response to that request. *See* Letter from Amanda J. Klingler, Docket No. FDA-2019-N-3065-0001 (Sept. 9, 2019) (describing the FOIA request, noting that the requested documents are necessary in order to comment on the proposed rule, and requesting that FDA produce the documents no later than September 15, 2019).

In addition, the sixty-day comment period is entirely inadequate given the complexity of the proposed rule. FDA has spent years working on this proposed rule, and it emphasizes the complex process that it has followed to arrive at its proposed warnings. *See* 84 Fed. Reg. at 42,778 (saying that "[t]he process FDA engaged in to develop and study the warnings was far more extensive than could be completed in the short [two-year] timeframe for the prior rule"). And yet it expects the public to provide all of its comments—including proposals for *alternative text and images for the warnings*, with supporting information demonstrating that those alternatives would promote greater public understanding of the risks of smoking, 84 Fed. Reg. 42,766—within sixty days. This is simply impossible. *See* Altria Letter, Docket No. FDA-2019-N-3065 (Sept. 5, 2019) (requesting a 30-day extension of the public comment period).

E. FDA may have made some of these errors because a court order forced it to rush through the final stages of the rule.
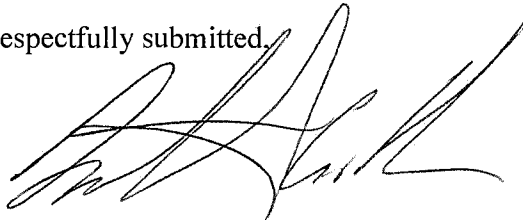
FDA's timeline for issuing the proposed rule was substantially accelerated by a decision from the U.S. District Court for the District of Massachusetts. The district court ordered FDA to issue the proposed rule by August 15, 2019, even though FDA had argued that it would need until April 2020. Defendant's Statement at 2, *American Academy of Pediatrics et al. v. FDA*, No. 1:16-cv-11985-IT (Oct. 5, 2018); Memorandum and Order at 5, *American Academy of Pediatrics et al. v. FDA*, No. 1:16-cv-11985-IT (Mar. 5, 2019). It is possible that some of the errors and shortcuts discussed above were simply a result of the Agency not having enough time to complete the proposed rule.

Notably, the district court also ordered FDA to complete the final rule by no later than March 15, 2020—a mere five months after the comment period will close. *Id* at 6*. It is apparent that five months is not enough time for the agency to properly consider and address the comments it will receive. For example, given how long FDA took to arrive at its proposed set of warnings, it is not realistic for it to seriously consider adopting a *different* set of warnings in the span of a few months, or even to consider meaningful changes to the proposed warnings. In effect, FDA has been ordered to conduct a meaningless notice-and-comment process.

*   *   *

RAIS is committed to working cooperatively with FDA to address important public-health issues regarding tobacco use in this country, including through appropriate cigarette warnings. But the proposed rule is irredeemably flawed. It violates bedrock First Amendment principles, and runs afoul of the Tobacco Control Act and the Administrative Procedure Act. And in some ways, that is no surprise: the Tobacco Control Act's graphic-warnings requirement violates the First Amendment, which means that any graphic-warnings rule will do so as well. As a result, FDA should withdraw the proposed rule and refuse to enforce the Act's unconstitutional graphic-warnings requirement.

Respectfully submitted,

Mitchell A. Neuhauser
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EXHIBITS TO RAIS GRAPHIC-WARNINGS COMMENTS

- Exhibit A: Reference List for RAIS Graphic-Warnings Comments

- Exhibit B: Selection of Publicly Available Studies, Reports, and Articles

- Exhibit C: Statement of Jonathan Klick, Ph.D, J.D.

- Exhibit D: Report of Professor Jan-Benedict Steenkamp

- Exhibit E: NERA Survey: Consumer Perceptions of Cigarette Warning Labels, Submitted By Samantha Iyengar, Ph.D.

- Exhibit F: Report of Dr. John E. Martin, Ph.D.

- Exhibit G: Declaration of Lawrence R. Brooks, MD

- Exhibit H: Declaration of Jonathan M. Davidorf, MD

- Exhibit I: Declaration of Mark O. Farber, MD

- Exhibit J: Declaration of Kim R. Jones, MD

- Exhibit K: Declaration of Robert Wagmeister, MD

- Exhibit L: Declaration of Rachael B. Claxton

- Exhibit M: Dr. Robert Hornik, Proposal for an Administrative Supplement to a Research Grant from the National Institutes of Health (Oct. 21, 2011).

- Exhibit N: Dr. Daniel D. Langleben, Application for Federal Grant from the National Institutes of Health (submitted on October 29, 2012).

- Exhibit O: Dr. James Thrasher, Annual Report to the National Institutes of Health Regarding Grant Funding (Mar. 16, 2016).

- Exhibit P: Letter From Caitlyn J. Ozier, King & Spalding LLP, To FDA (June 14, 2017).

Exhibit A

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Exhibit B

Hard copies of the publicly available studies, reports, and articles listed in Exhibit A are being filed in hard copy with FDA.

Effects of plain package branding and graphic health warnings on adolescent smokers in the USA, Spain and France

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ABSTRACT

Objective The purpose of this study is to provide an experimental test of the effects of plain pack branding and graphic health warnings (GHWs) in three different countries for an important and vulnerable population, that is, adolescents who are experimenting with smoking.

Methods The effects of plain pack branding (logo present, logo absent), and graphic visual warning level (absent, low, medium, high) are studied experimentally for their impact on adolescent cigarette craving, evoked fear, pack feelings and thoughts of quitting in the USA, Spain and France. A total of 1066 adolescents who were experimenting with smoking served as participants in the study. A quota sample produced 375 respondents in the USA, 337 in Spain and 354 in France.

Results Overall findings indicate that the GHWs were effective in impacting adolescent cigarette craving, evoked fear, pack feelings and thoughts of quitting. The plain pack effects were not as strong, yet reduced craving, increased fear, and decreased pack feelings for all three samples combined, and for US adolescent smokers individually, irrespective of the GHWs. For French adolescent smokers, plain pack effects for craving were limited to low/moderate GHW levels. For Spanish adolescent smokers, plain pack feeling effects were limited to the absence of the GHWs.

Conclusions The results show that plain packs can independently strengthen the more instantaneous, direct effects (short of quitting thoughts) found with the GHWs. Yet, the plain pack results were attenuated for Spanish and French adolescent smokers, who are currently exposed to GHWs.

INTRODUCTION

Tobacco use is the single most preventable cause of death in the world today, accounting for almost 6 million deaths each year.[1] In the USA, there are approximately 483 000 deaths annually due to smoking and an estimated 350 000 new, underage smokers.[2] Sadly, 88% of all adult smokers begin in their teens or younger, with smoking being described by many as a 'pediatric disease'.[2-4] Currently, cigarette-smoking rates for high school students have declined to 9.2%, yet the use of any tobacco product remains high at 24.6%.[5] Although research shows that graphic health warnings (GHWs) on tobacco packages have helped,[6] perhaps the most important initiative in an extension of the GHWs to curb adolescent smoking is the use of plain packs that remove all branding colours, imagery, logos, and trademarks, except for a small brand name identifier and the GHW.

The WHO has touted the 2011 Australian plain pack legislation as 'setting a new global standard' for control of a product that kills millions each year worldwide.[7] Recently, the UK, Ireland, and France are in the process of implementing plain packing, with Spain (and others) retaining the right for future use.[8 9] Although there are many studies of the impact of GHWs on adult smokers,[6 10 11] and a few examining effects of plain packs and warnings on adult smokers, experimental plain pack research is needed on one of the most important and vulnerable populations, that is, adolescents experimenting with smoking.

GHWs and experimental research

Currently, 176 countries (including France in 2004, Spain in 2005, yet not the USA) have ratified or accepted the WHO's Framework Convention on Tobacco Control (FCTC) treaty requiring tobacco warning information in the form of text, visual (eg, GHW), or a combination of the two (WHO 2003).[12] GHWs, offering a *visual* depiction of the health consequences associated with smoking, are now required in over 77 countries, beginning with Canada in 2001.[13] In 2005, the EU adopted a library of 42 (GHW) visuals for use with text warnings, and France and Spain began requiring GHWs beginning in 2011.[13] In the USA, although the Family Smoking Prevention & Tobacco Control Act (FSPTCA) (2009) mandated the use of the colour GHWs with text warnings, their use has been blocked by a US federal court decision.[6]

A wide variety of research studies have been conducted on GHWs involving many different outcomes.[6] Still, relatively few controlled experiments have been conducted to test the effectiveness of GHWs,[14-26] which are necessary to establish cause and effect relationships.[27 28] For example, experimental studies have shown that the level of graphicness affects quit thoughts for adolescent smokers, with both high and moderate graphic levels being more effective than low or no graphic warnings.[15 22]

Plain pack research

Brand and logo information ('trade dress') (eg, name, colour, design, shape) are important elements in developing brands by differentiating one brand from another in the minds of consumers.[29] Strong brand logos and identifying characteristics tend to aid brand recognition, convey consistent meaning to consumers, and evoke positive brand feelings.[30] As applied to tobacco packaging, eye-tracking research has shown that plain cigarette

packs (ie, packages with only a small, brand name identification and without colour brand logos) remove attention from brand information and shift it towards GHWs for non-smokers and weekly smokers, but not for daily smokers who consciously avoid the warnings.[31] [32] Also, plain tobacco packs displaying progressively fewer branding design elements are perceived to be increasingly unfavourable by adult smokers[33] and result in an increase in strong cognitive, emotional, motivational, and avoidance reactions.[34-37] In experimental auctions, bids from adult smokers are lowest for plain unbranded packs with prominent visual warnings.[38] [39] In a naturalistic field study, young adult UK smokers used plain packs for 2 weeks and regular packs for 2 weeks.[40] Results showed that the plain packs increased (1) negative feelings about the packs, (2) pack avoidance behaviour, and (3) quitting thoughts to a greater extent than regular packs. Similar results were found in a field study of plain packs among young adult, roll-your-own, smokers in France.[41] Yet, in another study, although standardised (plain) packs were shown to reduce cigarette craving over time, they did not affect adult smoker motivation to quit.[42]

Because prior plain pack studies have used adult smokers, an important question is "Will adolescent smokers react in the same way?" Focus groups with adolescents (not necessarily smokers) indicate that plain packs are likely to enhance the salience and impact of the graphic warning labels.[43] Other survey work with adolescents (again not necessarily smokers) has shown shifts over time in pack perceptions, brand image, and beliefs of harmful consequences due to a combined presentation of the GWHs and plain packs.[44] [45] Our experimental study across three different countries focuses on two key outcomes from GHWs and plain packs—that is, short-term cigarette craving[21] and longer-term thoughts of quitting.[22] We also examine separate main and interactive effects for GHWs and plain packs in our experimental design, as previous research has traditionally studied only perceptions of their combined effects. Based on this discussion, it is predicted that:

H1: Stronger GHWs will lead to (a) a greater reduction in adolescent smoker cigarette craving and (b) a greater increase in thoughts of quitting than will weaker GHWs (ie, with text-only warnings).

H2: Plain packages will lead to (a) a greater reduction in adolescent smoker cigarette craving and (b) a greater increase in thoughts of quitting than will packages with brand logo information.

H3: There will be an interaction between the GHWs and plain pack branding such that the effect of stronger GHWs is greater for plain packs than for packs with brand logo information, leading to (a) a greater reduction in adolescent smoker cigarette craving and (b) a greater increase in thoughts of quitting. Such branding differences are expected to be stronger for non-graphic (text-only) health warnings.

We address these predictions across and within three countries, two of which (Spain and France) currently require GHWs and one which does not (the USA).

METHODS
Sample and general procedure
Data collection
A professional marketing research firm, with expertise in research involving adolescent smokers and conducting international online surveys, was used to collect the data. A double consent procedure was employed, that is, parents were first contacted to obtain permission and then the adolescents were asked for permission. Participants were adolescents aged 13–18, split

evenly across the USA, France and Spain, who indicated that they smoked at least once in the past 30 days.[46] A set of academic linguistic experts and young adults fluent in the language for the sample were used to help translate the stimuli and questionnaire for both the pretest and main study from English (US) into French and Spanish. The stimuli and questionnaire were then back translated into English to ensure the intended meaning.

Pretest
A pretest of 150 adolescent smokers (50 US, 50 Spain and 50 France) was used to help select three graphic visuals (low, medium and high graphicness) from nine pictures depicting mouth cancer from around the world. (Mouth cancer has been noted as one of the most recognised and effective package warnings and is particularly relevant to the sample).[47] Three age quotas (ie, 13–14, 15–16 and 17–18), based on the University of Michigan Monitoring the Future data on adolescent smokers, were used to help ensure representative samples in all adolescent age groups. A 50/50 split was made on gender to ensure equal representation in the samples, and smoking status in the past 30 days[46] was screened as well. Each adolescent was exposed to a randomly-ordered set of nine pictures depicting mouth cancer and then asked a set of questions regarding perceived graphicness, evoked fear and fit with a text warning on mouth cancer under each picture. For the key measure of graphicness, each respondent evaluated the given picture on four, seven-point scales: graphic—not graphic; vivid—not vivid; powerful—weak; and intense—not intense; $\alpha=0.97$.[15] [22] Finally, one additional single item, seven-point measure assessed the degree to which respondents felt the picture fit a text warning of 'mouth cancer', and a second, seven-point measure assessed the perceived believability of the picture. The level of evoked fear from each picture was measured with four, seven-point scales: fearful—not fearful; afraid—not afraid; anxious—not anxious; and nervous —not nervous; $\alpha=0.97$.[15] [22] Standardised mean scores were calculated and CIs within each country showed items that were significantly different from one another ($p \leq 0.05$). The graphicness results for the moderate and low graphic visuals were consistent across all three countries aiding the selection of the picture for the moderate and low categories. The high graphic picture evaluation varied somewhat across three countries, with the selected picture providing the greatest consistency across all measures.

Main study procedure and design
The main study again used a double consent procedure (ie, parents gave their permission, then adolescents) before being screened on age, gender, and smoking status (in the past 30 days).[46] The study sample consisted of 1066 adolescents experimenting with smoking—375 in USA, 337 in Spain and 354 in France, with quotas producing a 50/50 split on gender and age categories of 15% (13–14 years.), 33% (15–16 years.), and 52% (17–18 years.) based on the University of Michigan Monitoring the Future data. Following screening questions, respondents were told they would be viewing a cigarette package and then asked some questions about it without any reference to warnings. After successful screening for consent and quotas, respondents were randomly assigned to one of the eight experimental versions of cigarette packs (see figure 1 for the English version). The top one-half of the package facing included the text warning and graphic visual health warning (if included), with the GHW taking up one-third of the total package facing. The bottom half of the pack facing included
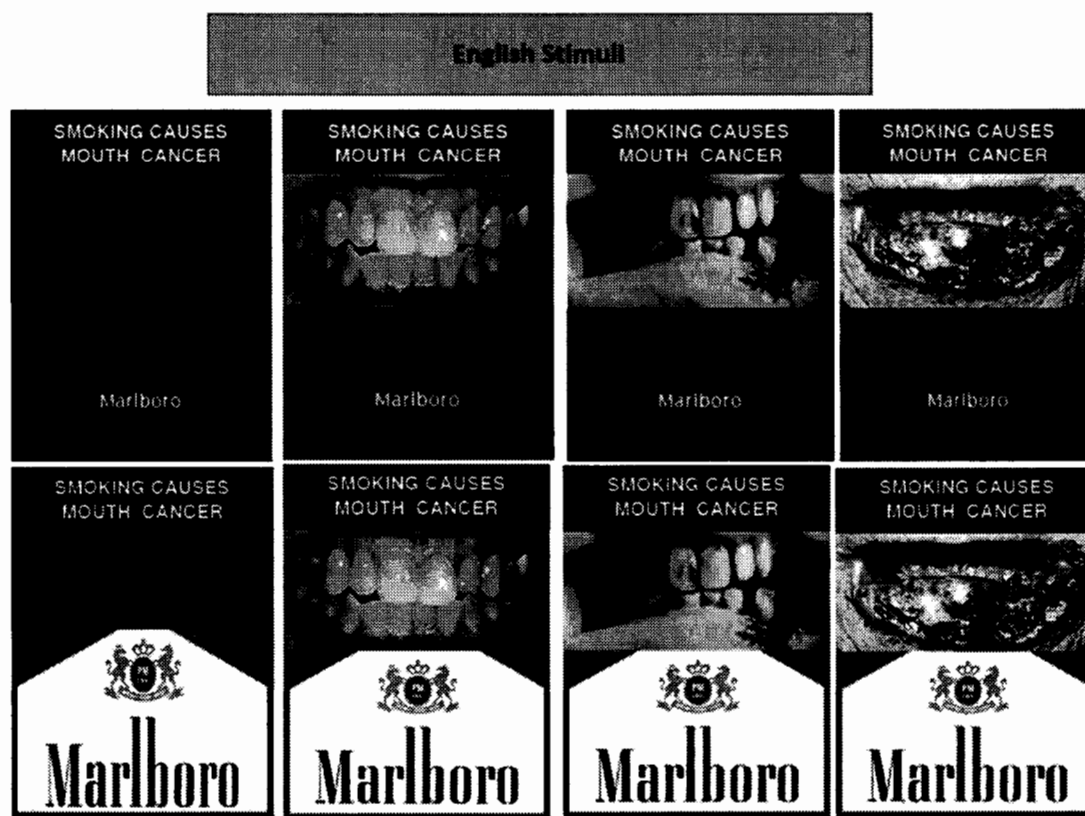
Figure 1 Examples of the plain pack branding and graphic health warnings manipulations.

either the traditional brand logo and colours or the plain pack version (brand name minimised in white on a drab olive background, similar to Australia's plain packs). Thus, the main study used a four (GHW level: absent/control, low, medium, high)×2 (plain pack branding: plain pack with minimised brand name and no brand logo or colour, traditional brand logo with current brand name and logo and colour) between-participants design. The leading brand available across all three countries (Marlboro) was used for pack stimuli.[48]

Main study measures

Key dependent variables of interest include cigarette craving (single-item, 6-point scale); evoked fear (4-item, 7-point scale, $\alpha=0.94$); pack feelings (3-item, 7-point scale, $\alpha=0.87$); and quitting thoughts (4-item, 7-point scale, $\alpha=0.81$). Cigarette craving was measured by asking respondents, "After having viewed the cigarette package, how much do you want to smoke a cigarette right now?" with end points of 'not at all'—'very much'.[21] The evoked fear measure asked respondents how the package made them feel with end points of 'not fearful'—'very fearful'; 'not afraid'—'very afraid'; 'not nervous'—'very nervous'; and 'not anxious'—'very anxious'.[15 22] For pack feelings, respondents were asked, 'Personally, when I looked at the cigarette pack, I felt...' 'embarrassed'—'not embarrassed', 'ashamed'—'not ashamed', and 'accepted'—'not accepted'.[40] Thoughts of quitting were measured on seven-point scales by the following: (1) 'The information shown on the cigarette package would help me quit smoking' ('strongly disagree—strongly agree'), (2) 'The information on the cigarette package motivates me to quit smoking' ('strongly disagree—strongly agree'), (3) 'How important is it for you to quit smoking?' ('not at all important—very important'), and (4)

'How often do you think about quitting smoking?' ('not often —very often').[22]

RESULTS

Manipulation checks were used to ensure participants recognised the brand information on the package and 90% recognised that they were exposed to the Marlboro brand across all treatments. Also, in the absence of graphic warnings, those exposed to the colour, brand logo condition (M=5.16) felt the package's brand was significantly brighter and more colourful (on a seven-point agreement scale to 'The package's brand was bright and colourful') than those exposed to plain packs (M=2.84; t=10.25; $p \leq 0.01$).

A multivariate analysis of covariance was first conducted to examine main effects for the GHWs, then for plain pack branding, and interaction effects between the GHWs and plain pack branding. Respondents' age, gender and familiarity with the Marlboro brand served as covariates. Also, the category breakdown for respondent 30-day smoking frequency[46] is as follows: 29.6% reported having smoked 1–2 days; 17.4% smoked 3–5 days; 11.8% smoked 6–9 days; 14.7% smoked 10–19 days; 8.0% smoked 20–29 days; and 18.5% reported having smoked all 30 days. Smoking rates for all 30 days in France (28%) were significantly higher than in Spain (15.7%) and the USA (12%; $\chi^2=25.74$, $p \leq 0.05$). Table 1 shows the overall multivariate and univariate findings for all countries combined as well as the effects within each country. Tables 2–4 then display the marginal means and SDs for each independent variable.

Effects of GHWs

Hypothesis 1 predicted that stronger graphic visual health warnings should result in a greater reduction in cigarette craving and

Table 1 Multivariate and univariate results for the effects of graphic health warning levels and plain packaging on adolescent smokers from the USA, Spain and France

Independent variables	Multivariate analysis of covariance results		Univariate F-values			
	Wilks' λ	F-value	Cigarette craving	Evoked fear	Pack feelings	Quit thoughts
Main effects						
All countries						
Graphic level (GL)	0.88	11.60***	21.55***	38.14***	17.18***	10.83**
Plain pack (PP)	0.98	6.03***	8.58***	5.42**	10.06***	0.21
Country (C)	0.97	4.40***	9.24***	8.99***	1.66	2.48*
USA						
GL	0.92	2.52***	5.88***	5.83***	4.18***	3.86***
PP	0.94	5.58***	4.03**	5.40**	3.94**	0.52
Spain						
GL	0.86	4.10***	8.44***	10.87***	3.11**	2.00
PP	0.99	0.90	2.61	1.35	1.01	0.20
France						
GL	0.75	8.77***	9.59***	28.44***	17.92***	5.51***
PP	0.97	2.42**	2.19	0.17	6.33**	0.03
Interaction effects						
All countries						
GL×C	0.96	1.64**	1.31	1.76*	3.83***	0.25
GL×PP	0.99	0.70	0.79	0.10	0.30	0.68
PP×C	0.99	1.17	0.03	1.06	0.52	0.65
GL×C×PP	0.97	1.51**	1.95*	1.56	2.04*	0.33
USA						
GL×PP	0.98	0.67	0.62	0.59	1.14	0.74
Spain						
GL×PP	0.95	1.45	0.47	0.43	2.59**	1.60
France						
GL×PP	0.94	1.78**	3.61**	2.46*	0.93	0.65

***p≤0.01; **p≤0.05; *p≤0.10. All values are adjusted for age, gender, and brand familiarity as covariates.

a greater increase in thoughts of quitting than will weaker (text-only) warnings. Supporting H1a and H1b, our findings in table 1 indicate that the graphic visual level had a significant and negative effect on cigarette craving (F(3,1065)=21.55, p≤0.01) and had a significant and positive effect on thoughts of quitting (F(3,1065)=10.83, p≤0.01). As shown in table 2, Bonferroni contrasts indicate that both high (M=1.83) and moderate (M=2.07) graphic visual warning levels significantly reduced cigarette craving for adolescent smokers compared to both control (no graphic) (M=2.67) and low graphic visual warning (M=2.53) conditions (all p≤0.05). Also in table 2, Bonferroni contrasts reveal that both high (M=4.76) and moderate (M=4.60) graphic visual warnings significantly increased adolescent smoker thoughts of quitting compared to both control (no graphic) (M=4.08) and low graphic visual warning (M=4.24) conditions (all p≤0.05). In addition, table 2 also shows similar effects of the graphic visual warning levels on evoked fear and pack feelings.

Effects of plain pack branding

Hypothesis 2 predicted that plain cigarette packages should lead to a greater reduction in cigarette craving and a greater increase in thoughts of quitting than will packages with the current brand logo information. The results in table 1 indicate that the plain pack treatment had a significant and negative effect on cigarette craving (F(1,1065)=8.58, p≤0.01) supporting H2a, yet did not support H2b predicting a positive effect on thoughts of quitting (F(1,1065)=0.21, p=0.65). Bonferroni contrasts in

table 3 show that the plan packs (M=2.15) significantly reduced cigarette craving for adolescent smokers compared to the brand logo condition (M=2.40) (p≤0.05). Yet, there were no significant differences between the plain pack condition (M=4.40) and brand logo condition (M=4.44) (p>0.05) on adolescent smokers' thought of quitting. However, table 3 shows that the plain pack condition significantly increased evoked fear and reduced pack feelings. Thus, although independent effects of the plain packs are shown on more immediate measures of craving, evoked fear and pack feelings, these effects did not extend to thoughts of quitting.

GHWs and plain pack branding

Hypothesis 3 predicted an interaction between GHWs and plain pack branding. It was predicted that stronger graphic visual health warnings and the absence of brand logo information will lead to (a) a greater reduction in cigarette craving and (b) a greater increase in thoughts of quitting than with weaker graphic visual health warnings and the presence of brand logo information. The branding differences also should be stronger for non-graphic (text-only) health warnings. Yet, the results in table 1 did not support H3a for a graphic warning×plain pack effect on cigarette craving (F(3,1065)=0.79, p=0.50), nor H3b for a graphic warning×plain pack effect on thoughts of quitting (F(3,1065)=0.68, p=0.56). Thus, separate (independent) main effects occurred for the graphic warnings and plain packs on cigarette craving and for graphic warnings on quitting thoughts. Though there were no significant 2-way graphic warning×plain

Table 2 Means (and SDs) for the effects of graphic level (GL) conditions on adolescent smokers from the USA, Spain and France

Graphic level	Craving	Evoked fear	Pack feelings	Quit thoughts
All countries				
Control (a)	2.67 (1.55)^{c,d}	3.37 (1.75)^{c,d}	4.15 (1.62)^{c,d}	4.08 (1.59)^{c,d}
Low (b)	2.53 (1.50)^{c,d}	3.42 (1.73)^{c,d}	4.03 (1.66)^{c,d}	4.24 (1.56)^{c,d}
Moderate (c)	2.07 (1.31)^{a,b}	4.11 (1.69)^{a,b,d}	3.49 (1.54)^{a,b}	4.60 (1.60)^{a,b}
High (d)	1.83 (1.26)^{a,b}	4.66 (1.62)^{a,b,c}	3.35 (1.57)^{a,b}	4.76 (1.40)^{a,b}
USA				
Control (a)	2.49 (1.58)^{c,d}	3.84 (1.94)^{d}	4.10 (1.68)^{c,d}	4.24 (1.72)^{d}
Low (b)	2.16 (1.28)	4.02 (1.71)^{d}	3.68 (1.55)	4.36 (1.61)
Moderate (c)	1.75 (1.02)^{a}	4.52 (1.66)	3.37 (1.50)^{a}	4.80 (1.53)
High (d)	1.84 (1.42)^{a}	4.81 (1.84)^{a,b}	3.39 (1.69)^{a}	4.86 (1.41)^{a}
Spain				
Control (a)	2.58 (1.52)^{c,d}	3.31 (1.60)^{c,d}	4.06 (1.60)^{d}	4.10 (1.57)
Low (b)	2.50 (1.53)^{c,d}	3.50 (1.69)^{d}	3.66 (1.60)	4.30 (1.65)
Moderate (c)	1.95 (1.27)^{a,b}	4.02 (1.67)^{a}	3.66 (1.61)	4.52 (1.63)
High (d)	1.71 (1.03)^{a,b}	4.57 (1.52)^{a,b}	3.34 (1.44)^{a}	4.62 (1.46)
France				
Control (a)	2.93 (1.52)^{d}	2.97 (1.58)^{c,d}	4.28 (1.59)^{c,d}	3.95 (1.46)^{d}
Low (b)	2.92 (1.60)^{d}	2.73 (1.52)^{c,d}	4.76 (1.59)^{c,d}	4.06 (1.41)^{d}
Moderate (c)	2.54 (1.50)^{d}	3.73 (1.67)^{a,b,d}	3.48 (1.52)^{a,b}	4.47 (1.64)
High (d)	1.93 (1.30)^{a,b,c}	4.59 (1.47)^{a,b,c}	3.31 (1.57)^{a,b}	4.75 (1.33)^{a,b}

Superscripts adjacent to the means *in a given column* indicate significant differences ($p \leq 0.05$ or better) between cells based on Bonferroni contrasts. All values in mean tables are adjusted for age, gender, and brand familiarity as covariates.

pack effects overall, a significant 3-way multivariate effect was found across the dependent variables in table 1 (Wilks' $\lambda = 0.97$; $F = 1.51$, $p \leq 0.05$). As discussed below, significant 2-way effects for graphic warning×plain pack occurred for cigarette craving in France and for pack feelings in Spain.

Country effects

As noted in table 1, there were main effects for country (ie, USA, Spain or France) on cigarette craving ($F(2,1065) = 9.24$, $p \leq 0.01$) and evoked fear ($F(2,1065) = 8.99$, $p < 0.01$). Bonferroni contrasts in table 4 reveal that cigarette craving was

Table 3 Means (and SDs) for the effects of plain pack (PP) conditions on adolescent smokers from the USA, Spain and France

Plain pack	Craving	Evoked fear	Pack feelings	Quit thoughts
All countries				
Plain pack (a)	2.15 (1.38)^{b}	4.01 (1.78)^{b}	3.60 (1.60)^{b}	4.40 (1.53)
Branded pack (b)	2.40 (1.50)^{a}	3.77 (1.76)^{a}	3.91 (1.64)^{a}	4.44 (1.58)
USA				
Plain pack (a)	1.92 (1.26)^{b}	4.51 (1.83)^{b}	3.47 (1.56)^{b}	4.48 (1.53)
Branded pack (b)	2.20 (1.45)^{a}	4.08 (1.81)^{a}	3.80 (1.67)^{a}	4.67 (1.65)
Spain				
Plain pack (a)	2.07 (1.30)	3.95 (1.62)	3.59 (1.55)	4.42 (1.56)
Branded pack (b)	2.30 (1.47)	3.75 (1.75)	3.76 (1.61)	4.34 (1.61)
France				
Plain pack (a)	2.46 (1.57)	3.54 (1.59)	3.75 (1.56)^{b}	4.30 (1.47)
Branded pack (b)	2.69 (1.62)	3.47 (1.69)	4.16 (1.61)^{a}	4.32 (1.55)

Superscripts adjacent to the means *in a given column* indicate significant differences ($p \leq 0.05$ or better) between cells based on Bonferroni contrasts. All values in mean tables are adjusted for age, gender, and brand familiarity as covariates.

Table 4 Means (and SDs) for the effects of country (C) conditions on adolescent smokers from the USA, Spain and France

Country	Craving	Evoked fear	Pack feelings	Quit thoughts
USA (a)	2.09 (1.37)^{c}	4.14 (1.83)^{c}	3.76 (1.63)	4.57 (1.59)
Spain (b)	2.19 (1.39)^{c}	3.93 (1.69)^{c}	3.64 (1.58)	4.38 (1.58)
France (c)	2.54 (1.53)^{a,b}	3.60 (1.72)^{a,b}	3.86 (1.68)	4.31 (1.49)

Superscripts adjacent to the means *in a given column* indicate significant differences ($p \leq 0.05$ or better) between cells based on Bonferroni contrasts. All values in mean tables are adjusted for age, gender, and brand familiarity as covariates.

significantly stronger in the France ($M = 2.54$) than in either Spain ($M = 2.19$) or the USA ($M = 2.09$; both $p \leq 0.01$). Similarly, evoked fear was significantly less in France ($M = 3.60$) than in either Spain ($M = 3.93$) or in the USA ($M = 4.14$; both $p \leq 0.05$).

We also offer an examination of separate intracountry effects (with smaller cell sizes) for the graphic warnings and plain packs in table 1. The results for the US are identical to the overall effects. In Spain, a significant graphic warning×plain pack effect was found for pack feelings (see table 1). Specifically, plain packs ($M = 3.58$) versus branded logos ($M = 4.54$) significantly reduced pack feelings in the absence of the GHWs ($F(1,85) = 8.63$, $p \leq 0.01$). (There were no plain pack effects for other GHW conditions.) In France, a significant graphic warning×plain pack effect occurred for cigarette craving (see table 1). In particular, plain packs ($M = 2.55$) versus branded logos ($M = 3.29$) significantly reduced craving under low GHWs ($F(1,89) = 4.72$, $p \leq 0.05$) and moderate GHWs (plain pack $M = 2.17$; branded logos $M = 2.91$; $F(1,85) = 5.57$, $p \leq 0.05$). (There were no plain pack effects for the other GHW conditions.) Again, caution is in order due to the smaller cell sizes and reduced statistical power in these intracountry analyses.

DISCUSSION

Most experimental research on the GHWs has occurred in a limited set of countries such as the USA. Yet, how will different levels of graphicness affect adolescent smokers across other countries than the USA, some of which have had the warnings in place for some time (eg, France, Spain)? More importantly, can plain packs (ie, without brand colours and logos) *independently* add to these effects for adolescent smokers? Will plain pack effects vary by country? Our research with over 1000 adolescents experimenting with smoking in the USA, France and Spain sought to answer these questions.

Our results across three countries indicate that graphicness impacts quit thoughts, with high and moderate GHWs significantly increasing adolescent smokers' thoughts of quitting compared to both control (no graphic) and low GHW conditions. In turn, both plain packs and graphicness are found to separately impact more immediate-term measures of reduced cigarette craving, increased evoked fear and decreased pack feelings. In general, effects of GHWs in Spain and France are greater than plain pack effects, and this appears reasonable given outcomes, such as evoked fear and craving, that may be more likely for a graphic pictorial than for removal of brand logo information that may affect brand identification and consumer–brand relationships. Also, note that results are tempered by a significant, overall 3-way effect (graphic warning level×plain pack×country) on the dependent measures. For Spanish adolescent smokers, the plain packs reduced pack feelings without exposure to the GHWs (control condition). In France, the plain packs significantly reduced cigarette craving with exposure to

the low and moderate GHWs. Some habituation and/or react-ance may be present for French adolescent smokers with their higher smoking frequency and reduced fear when exposed to plain packs with high GHW levels.

Limitations and future research issues

Our experimental study manipulated GHWs and plain pack branding for adolescent smokers across three countries; offering a high degree of internal validity. However, although the online exposure context, sample focus, stimuli tested, measures used, and parental and adolescent consents (to meet IRB require-ments) are consistent with prior tobacco warning reseach,[15 22] they could serve to limit the generalisability of findings. There certainly are other warning themes to study beyond mouth cancer, as well as for other countries, smoking frequencies/situa-tions[46] (eg, progression from experimenters to any 30-day use to daily smokers), plain pack variations,[33] brand variant descrip-tors (eg, colour, flavour, filter),[49] and other brands and tobacco products (eg, e-cigarettes, hookah, cigars, cigarillos, smokeless tobacco).[50] Also, mediation analysis may reveal interesting path-ways to quitting from the plain packs and GHWs. Future research might consider using longitudinal data to examine any possible wear-out patterns in countries currently using the plain packs (eg, Australia, Ireland, and the UK, as well as France in 2016). Efforts in this regard will help contribute to a better understanding of how adolescents at risk of becoming lifetime smokers will react to countermeasures, like plain packs and GHWs, aimed at reducing dependence on tobacco.

CONCLUSION

As found in previous GHW research,[15 22] the level of graphic-ness remains important in affecting quit thoughts for adolescent smokers, with both high and moderate graphic levels being more effective than low or no graphic warnings. Our overall results also show that plain pack branding can add to GHW

effectiveness—yet only for the more immediate measures of cig-arette craving, evoked fear and pack feelings. No doubt, the impact of plain pack branding may take some time and longitu-dinal assessments may be in order. Country effects for the plain packs indicate that they potentially can aid French adolescent smokers in reducing cigarette cravings—yet only at either low or moderate GHW levels. In Spain, the plain packs reduced pack feelings without exposure to the GHWs (control condition). Yet, the main effects of plain pack branding for Spanish and French adolescent smokers were not significant, perhaps imply-ing that the removal of coloured brand logos for this global and US-based brand is not as important to Spanish and French ado-lescent smokers as for US smokers for these specific variables. For the US, without either GHWs or plain packs currently appearing on cigarette packs, our plain pack treatment reduced cigarette craving, increased evoked fear and lessened pack feel-ings without the need of GHWs. Overall, plain packs are found to add to GHWs for more immediate effects (eg, reducing cigar-ette craving, increasing evoked fear, and decreasing pack feel-ings) depending on the adolescent smoker's prior exposure in different countries.

What this paper adds

- ▶ Plain pack branding on cigarette packaging is an important and emerging international tobacco control policy. Plain packs often appear in conjunction with graphic health warnings (GHWs) on cigarette packs. This paper builds on the existing literature by examining what the separate and interactive effects might be for plain packs and GHWs. Moreover, we extend previous research on GHWs and plain packs to an important segment—adolescent smokers—and do so across three different countries.
- ▶ Our between-participants experiment with over 1000 adolescent smokers across the USA, Spain and France studies the effects of plain pack branding (logo present, logo absent) and GHW level (absent, low, medium, high) on adolescent cigarette craving, evoked fear, pack feelings and thoughts of quitting.
- ▶ Overall results indicate graphicness impacts quit thoughts; whereas plain packs and graphicness affect more immediate measures of craving, fear/emotion, and pack feelings. The manipulations were less effective for quit thoughts for adolescent smokers in Spain and France, who are currently exposed to GHWs.
- ▶ Plain packs can independently strengthen the more instantaneous, direct effects found with the GHWs.

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Testing warning messages on smokers' cigarette packages: a standardised protocol

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ABSTRACT

Purpose Lab experiments on cigarette warnings typically use a brief one-time exposure that is not paired with the cigarette packs smokers use every day, leaving open the question of how repeated warning exposure over several weeks may affect smokers. This proof of principle study sought to develop a new protocol for testing cigarette warnings that better reflects real-world exposure by presenting them on cigarette smokers' own packs.

Methods We tested a cigarette pack labelling protocol with 76 US smokers ages 18 and older. We applied graphic warnings to the front and back of smokers' cigarette packs.

Results Most smokers reported that at least 75% of the packs of cigarettes they smoked during the study had our warnings. Nearly all said they would participate in the study again. Using cigarette packs with the study warnings increased quit intentions ($p<0.05$).

Conclusions Our findings suggest a feasible pack labelling protocol with six steps: (1) schedule appointments at brief intervals; (2) determine typical cigarette consumption; (3) ask smokers to bring a supply of cigarette packs to study appointments; (4) apply labels to smokers' cigarette packs; (5) provide participation incentives at the end of appointments; and (6) refer smokers to cessation services at end of the study. When used in randomised controlled trials in settings with real-world message exposure over time, this protocol may help identify the true impact of warnings and thus better inform tobacco product labelling policy.

Clinical trial number NCT02247908.

INTRODUCTION

For much of the world, tobacco product packaging is a key part of marketing efforts to make tobacco use appealing.[1–3] In contrast, warnings on tobacco product packages accurately convey the many health risks of tobacco to discourage smoking initiation and increase cessation.[4] Information on the effectiveness of these warnings can guide policymakers as they consider new warnings and develop regulations. In the more than 100 countries that already have cigarette pack labelling policies in place,[5] testing the impact of potential cigarette pack warnings can guide selection of warnings with the greatest impact.

Research on cigarette pack warnings currently focuses on population-based observational studies of smoking behaviour and on laboratory experiments. Longitudinal observational studies have found increased cessation behaviour after countries introduced new health warnings on cigarette

packs.[6–9] These observational studies have high external validity, but they do not rule out alternative explanations for the association of the changes in labelling and behaviour change. Experiments on exposure to cigarette pack warnings in laboratory settings can offer much stronger evidence that warnings cause observed changes in beliefs and behaviour.[10 11] While a large experimental literature has developed, these experiments use very brief exposure to warnings; assess non-behavioural short-term outcomes, such as attitudes or quit intentions, instead of smoking behaviour; and, yield results that need corroboration outside of a controlled research setting.

It will be helpful to develop a way to deliver new messages on cigarette packs that smokers use daily in order to expand the external validity of experimental research on cigarette warnings. This will ensure a meaningful warning 'dose' that replicates the frequency and duration of warning exposure in the real world. For example, a pack-a-day smoker sees a cigarette pack at least an estimated 7300 times per year (>20 views/day$\times365$ days/year).

Several studies have tested warnings by providing mocked-up cigarette packs to participants, but most of these studies used a one-time, brief exposure that does not replicate message dose in the real world.[10 12–18] At least five studies have used mocked-up packs for a longer period of time.[19 20] A 2001 study conducted in France, Switzerland and Belgium mailed 485 adult smokers cardboard boxes with one of four antismoking messages selected by the smoker at recruitment. Study materials instructed participants to place their cigarette packs in the boxes for 4 weeks, but few did so.[20] A 2010 study in Scotland provided 140 adult smokers with 14 plain cigarette packs that had warnings but no brand information or logos, asking participants to transfer their own cigarettes into the supplied packs for 2 weeks. Only 34% of participants completed the study as intended.[19] A recent US study provided smokers with free cigarettes and labelled the packs with health warnings for 4 weeks. During the study, participants collected their cigarette butts and brought them to study appointments. This study used an innovative method for labelling cigarette packs, but the results may have been influenced by receipt of free cigarettes and saving the cigarette butts.[21] Two additional recent studies in the US had smokers apply warning labels to their own cigarette packs, which may be an intervention in its own right, and both studies had short follow-up periods (3–7 days).[22 23] While these studies' methods are promising because they more closely replicate real-world

message dose, we need strategies with high protocol adherence and longer follow-up periods. Tobacco control research would benefit from a way to test health warnings on cigarette packs that allows for random assignment to warning conditions, adds realism and maintains high protocol adherence.

To that end, we tested a new cigarette pack labelling and carrying protocol with adult smokers in two proof-of-principle pilot studies. We aimed to assess whether the pack labelling and carrying protocol (1) is feasible and has high adherence for assessing smokers' reactions to cigarette pack warnings in a real-world setting and (2) is sensitive to changes in psychosocial outcomes.

MATERIALS AND METHODS
Participants
Pilot study 1
From February to March 2013, we recruited 30 smokers ages 18 or older who we observed smoking cigarettes in public places in North Carolina, USA, or who received referrals from study participants. We defined current smoking as having smoked at least 100 cigarettes during one's lifetime and now smoking every day or some days, and we excluded pregnant women, people who smoke only roll-your-own cigarettes and cigarillo-only smokers.

Pilot study 2
In July and August 2014, we recruited an additional 48 smokers using the same eligibility criteria as Pilot Study 1. We used a variety of recruitment methods, including newspaper ads, flyers and email lists.

Procedures
Pilot study 1
A research assistant explained the study to participants and obtained written informed consent. We provided participants with an $80 financial study incentive in cash and accompanied them to a nearby store, where we asked them to purchase the amount of cigarette packs they would normally smoke over 2 weeks as determined in the initial screening. We randomly assigned participants to receive one of nine graphic warnings. In 2011, the US Food and Drug Administration (FDA) proposed these nine warnings for implementation, but the warnings were later challenged in court and are not currently in use.[24] At the time of the study, US cigarette packs also included one of four text-only warnings on one side of the pack; these warnings have been in circulation since 1985. Then, participants completed a baseline survey on a tablet computer while staff removed the package cellophane and applied the same graphic warning labels to the top half of the front and rear panels of participants' cigarette packs, in accordance with the proposed FDA requirements (figure 1). As applying the labels on the top half of the front panel sealed the flip-top box shut, staff cut through the label to allow the box to again open freely. Participants returned to the study offices to complete a follow-up computer survey 2 weeks later and received an additional $50 cash incentive. After completing the follow-up visit survey, each participant received information about a local smoking cessation programme.

Pilot study 2
Procedures for Pilot Study 2 were similar to Pilot Study 1. After obtaining written informed consent, we randomly assigned participants to receive one of five graphic warnings, four of which were also used in Pilot Study 1. Participants visited our study offices at baseline and then weekly for 4 weeks, completing a

Figure 1 Example of graphic warning label on pack.

survey on the computer at each visit. Smokers brought 8 days' worth of cigarettes to the first four appointments. While participants were taking the survey, we labelled their packs using the same procedures as in Pilot Study 1. Participants received a cash incentive at the end of each visit in an envelope marked 'payment for survey completion.' Cash incentives totalled $185. At the final appointment, each participant received information about a local smoking cessation programme. Two of the 48 participants withdrew from the study. The University of North Carolina Institutional Review Board approved the procedures for both pilot studies.

Measures
Prior to the studies, we refined the survey instruments by conducting cognitive interviews with 17 adult smokers.[25] Baseline and follow-up surveys applied measures adapted from prior studies, including knowledge of smoking health risks (3 items),[26] perceived likelihood of harm from smoking (2 items),[27] worry about the harms of smoking (1 item),[28] subjective norms (3 items),[29] positive smoker prototypes (7 items),[30-32] negative smoker prototypes (5 items),[30-32] self-efficacy to quit smoking (3 items)[29] and quit intentions (3 items).[33] Cronbach's α for multi-item scales was 0.70 or higher in both studies, except for self-efficacy in Pilot Study 1 (α=0.69). We also measured whether participants attempted to quit smoking (defined as not smoking for at least 24 h because they were trying to quit smoking) or successfully stopped smoking during the study (defined as not smoking for at least 7 days).

The follow-up surveys assessed noticing the warning, whether people talked to others about the warning, avoidance of the warning, emotional reactions to the warning,[34] participant satisfaction with study procedures, the number of cigarettes smoked from labelled and unlabelled packs and unprompted recall of

the warning image. Two raters independently coded whether each participant correctly recalled the image in their assigned warning, with perfect agreement.

Finally, in Pilot Study 1, several open-ended questions assessed attitudes toward the study protocol. Two raters independently coded whether open-ended responses indicated that smokers thought the study was giving them free cigarettes. A coauthor resolved all coding discrepancies. The survey instruments are available online: http://www.unc.edu/~ntbrewer.

Data analysis

We calculated descriptive statistics to summarise demographic information and process measures. We assessed changes between baseline and follow-up using paired t tests or McNemar χ^2 tests. For continuous variables with non-normal distribution (by Q–Q plots and Kolmogorov-Smirnov tests of normality), we used Wilcoxon signed-rank tests, a non-parametric equivalent of the paired t test. Analyses used SPSS Statistics V.20 and Stata/IC V.13.1. The two Pilot Study 2 participants who withdrew from the study were excluded from analyses. We set test critical α value to 0.05 and used two-tailed tests.

RESULTS

Smokers' mean age was 30 years in Pilot Study 1 and 43 years in Pilot Study 2 (table 1). Fewer than half of participants were white and about one-third were African-American. Most

Table 1 Participant demographics

	Pilot study 1 (n=30), %	Pilot study 2 (n=46), %
Age		
18–24 years	40	4
25–39 years	33	37
40–54 years	27	33
55+ years	0	26
Mean (SD)	30 (11)	43 (12)
Sex		
Female	40	57
Sexual orientation		
Straight	90	89
Gay	3	9
Bisexual	7	2
Hispanic ethnicity		
No	90	87
Yes	10	13
Race		
Asian	7	4
Black	27	35
White	43	44
Other/multiracial	23	17
Education		
High school degree or less	33	20
Some college	50	50
College graduate	10	24
Graduate or professional degree	7	7
Low income		
No	31	41
Yes	69	59
Cigarettes smoked per day		
Mean (SD)	12 (9)	11 (8)

smokers (69% in Pilot Study 1 and 59% in Pilot Study 2) were low-income, defined as being at or below 200% of the US federal poverty level. At baseline, participants in Pilot Study 1 smoked an average of 12 cigarettes per day (SD=9) and participants in Pilot Study 2 smoked an average of 11 cigarettes per day (SD=8).

Exposure to labels

Study participants reported high rates of adherence to smoking cigarettes only from labelled packs. Around 90% of smokers reported that at least three quarters of the cigarettes smoked during the study were from labelled packs (figure 2). Ninety per cent of smokers in Pilot Study 1 and 93% of smokers in Pilot Study 2 correctly recalled the image on their assigned labels. At follow-up, most (93% in Pilot Study 1 and 89% in Pilot Study 2) smokers reported noticing the warning sometimes, often, or all of the time (table 2). About half of smokers tried to avoid thinking about the labels sometimes, often, or all the time. Similarly, 43% of smokers in Pilot Study 1 and 46% of smokers in Pilot Study 2 tried to avoid looking at the labels sometimes, often, or all of the time.

Outcomes at follow-up

About half (50% in Pilot Study 1 and 41% in Pilot Study 2) of participants reported that the warnings caused them to think about the harmful effects of smoking somewhat, quite a bit, or very much. Almost all participants (97% in Pilot Study 1 and 93% in Pilot Study 2) reported talking to someone about the warnings during the study.

Changes in outcomes

Endorsement of positive smoker prototypes decreased between baseline and follow-up in both studies (p<0.05, table 3). Likewise, quit intentions increased in both studies (p<0.05). Worry about the harms of smoking increased in Pilot Study 1 (p=0.01) but not in Pilot Study 2. Knowledge and perceived likelihood of harm increased in Pilot Study 2 (p<0.05), but not in Pilot Study 1. The 2-week outcomes for Pilot Study 2 showed the same pattern as the 4-week outcomes (data not shown), except for cigarettes smoked per day which dropped to a mean of 9.10 (SD=6.81) from 11.11 (SD=7.44) at baseline (p=0.02).

The mean number of cigarettes smoked per day did not change between baseline and follow-up in either study. Ten per cent of Pilot Study 1 participants and 20% of Pilot Study 2 participants stopped smoking for at least 24 h during the study. No participants successfully quit smoking during Pilot Study 1. During Pilot Study 2, two participants had quit smoking by week 2 but they resumed by week 4, and one participant quit between weeks 2 and 4.
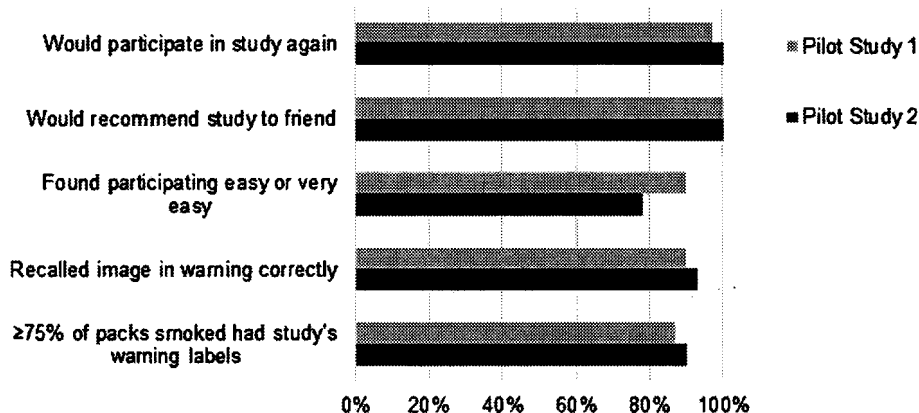
Process measures

Retention was very high in both studies (100% in Pilot Study 1 and 96% in Pilot Study 2). Nearly all participants said that they would probably or definitely participate in the study again, and 100% said they would probably or definitely recommend the study to a friend (figure 2). Most smokers (90% in Pilot Study 1 and 78% in Pilot Study 2) found participating in this study to be easy or very easy.

About a third (11/30) of Pilot Study 1 smokers said in exit interviews that they thought the study was buying them cigarettes as our staff had prepaid them and escorted them to the store so they could buy cigarettes at the baseline interview. To address these concerns, we asked Pilot Study 2 participants to bring an

Figure 2 Process evaluation measures for cigarette pack labelling proof of principle studies.

Would participate in study again

Would recommend study to friend

Found participating easy or very easy

Recalled image in warning correctly

≥75% of packs smoked had study's warning labels

■ Pilot Study 1

■ Pilot Study 2

0% 20% 40% 60% 80% 100%

eight-day supply of cigarettes with them to the study visits every week for 4 weeks. Most participants did not find this task to be burdensome: 15% of participants reported that it was difficult to bring in 8 days' worth of cigarettes, 30% said it was neither difficult nor easy, and 54% said it was easy or very easy.

DISCUSSION

Our proof of principle studies of placing warnings on real-world cigarette packages for an extended period of time suggests that our proposed protocol is feasible. The protocol had low attrition, high adherence and allowed assessment of impact over time. Most smokers complied with the study protocol and reported high levels of satisfaction with the procedures. Thus, this new pack carrying protocol offers the potential for both experimental control and greater real-world dose than exposures in brief lab studies.

The original protocol (Pilot Study 1) provided a financial incentive immediately before the smoker purchased cigarettes because we were concerned that low-income smokers could not afford the up-front costs of buying 2 weeks' worth of cigarettes at one time. However, we believe that our revised protocol (Pilot Study 2) may pose fewer risks to smokers. In the USA, lower-income populations smoke at higher rates than their

higher-income counterparts,[35] and, accordingly, research shows that most smokers do not purchase cigarettes in bulk, but rather by the pack.[36] Losing large numbers of smokers who cannot afford to purchase cigarettes in bulk would, in turn, limit the generalisability of cigarette pack labelling studies using such a protocol. However, many Pilot Study 1 participants believed that the study gave them free cigarettes, which could potentially increase smoking. Studies suggest lower prices encourage cigarette consumption.[37] Fortunately, cigarette consumption did not increase, while quit intentions did increase.

Another potential concern is whether having more cigarettes on hand might make participants smoke more, especially if they are not accustomed to purchasing packs in bulk. The empirical impact of stockpiling cigarettes on smoking behaviour is unknown. Smokers can save money by purchasing cigarettes in bulk (eg, cartons) rather than by the pack, but many smokers elect to ration their purchase quantities and impose additional transaction costs to limit their smoking.[38 39] We suggest keeping the length of time between study appointments at 1 week, which will limit the number of cigarette packs that participants will have on-hand at one time, thus reducing the potential risk that participants will smoke more. Future research should try to assess unintended consequences of stockpiling packs.

Table 2 Outcomes at follow-up

	Pilot study 1 (n=30)	Pilot study 2 (n=46)	
	2 week follow-up (%)	2 week follow-up (%)	4 week follow-up (%)
Psychosocial			
Noticed the warning*	93	89	78
Talked to anyone about the warnings*	97	93	96
Tried to avoid thinking about the warning*	43	50	30
Tried to avoid looking at the warning*	43	46	35
Felt (as a result of viewing the warning)†			
Depressed	10	4	4
Disgusted or grossed out	20	11	7
Guilty	10	11	9
Sad	13	7	9
Worried or anxious	20	5	2
Warning caused them to think about the harmful effects of smoking	50	41	39
Behavioural			
Quit attempt, 1 or more days	10	17	20
Quit smoking	0	4	2

*Responded 'sometimes,' 'often,' or 'all of the time' rather than 'never' or 'almost never'.
†Responded 'very' or 'completely,' rather than 'not at all,' 'a little,' or 'somewhat'.

Table 3 Changes in outcomes

	Pilot study 1 (n=30)			Pilot study 2 (n=46)		
	Baseline mean (SD)	2-week follow-up mean (SD)	p Value	Baseline mean (SD)	4-week follow-up mean (SD)	p Value
Knowledge of smoking health risks	2.47 (0.82)	2.63 (0.72)	0.17	2.67 (0.73)	2.93 (0.44)	<0.01*
Perceived likelihood of harm	2.93 (0.12)	3.10 (1.30)	0.39	3.20 (1.09)	3.59 (1.13)	0.02*
Worry	2.86 (1.06)	3.38 (1.08)	0.01*	3.02 (1.00)	3.09 (1.05)	0.42
Subjective norms	4.07 (0.95)	4.16 (0.87)	0.69	4.30 (0.83)	4.42 (0.77)	0.19
Smoker prototypes—positive	2.14 (1.07)	1.88 (0.92)	0.03*	1.98 (0.83)	1.47 (0.60)	<0.01*
Smoker prototypes—negative	1.93 (0.86)	1.83 (0.85)	0.15	1.68 (0.60)	1.73 (0.97)	0.76
Self-efficacy	3.27 (0.96)	3.53 (0.81)	0.10	3.46 (0.99)	3.73 (1.03)	0.06
Quit intentions	2.52 (1.06)	2.89 (1.10)	0.04*	2.26 (0.97)	2.93 (1.19)	<0.01*
Cigarettes smoked per day	11.59 (9.31)	11.58 (9.78)	0.99	11.11 (7.44)	9.98 (8.29)	0.24

*p<0.05.

Having participants bring their own cigarettes to study appointments decouples cigarette purchasing from receiving payment. Moreover, it appears that low-income smokers in our study were not deterred by having to purchase cigarettes in advance as part of the protocol as more than half of Pilot Study 2 participants were at or below 200% of the US federal poverty level. It remains possible that other low income smokers were unable to participate in the study.

Our findings point to a new pack labelling protocol with six steps: (1) schedule appointments 1 week apart; (2) determine daily cigarette consumption through smokers' self-report; (3) ask smokers to purchase and bring to the study appointments the amount of cigarette packs they would normally smoke between appointments, with an extra supply to buffer against cancellations and allow for greater than expected use; (4) during study appointments, apply labels to smokers' cigarette packs in-person by removing the top of the cellophane wrapping from the cigarette packs and applying self-adhesive labels with warnings directly to the packs, to prevent smokers from inadvertently removing the label with the wrapping; (5) provide study participation incentives at the end of the appointments and clearly communicate that the payment is for survey completion to reduce the possibility that participants will believe that the payments equate to receiving free cigarettes; and (6) refer smokers to cessation services at study completion or directly help smokers who want to quit. Table 4 gives the rationale for each protocol step. We implemented the six steps of this protocol successfully in Pilot Study 2.

Strengths of the study include establishing the feasibility of a new pack labelling protocol in a field study with current smokers, followed over time. As we studied a convenience sample recruited in a single location, the generalisability of our findings remains to be established. By labelling cigarette packs that smokers were currently using, we tested novel warnings alongside the standard US text-only warnings that we did not obscure. Depending on the brand, the warnings may have covered some of the branding or colour of the cigarette packs. In these cases, we may have overestimated the impact of the warning, as obscuring the branding may make cigarettes less appealing to smokers.[40 41] We relied on self-report to measure protocol adherence, but the extent to which self-reported adherence reflects actual adherence is unknown. We tested only methods for labelling cigarette packs, and we are unable to determine the utility of this protocol for other tobacco products. Finally, the small sample size limited statistical power to detect changes in psychosocial and behavioural outcomes.

Given the compelling need for better strategies to test the efficacy of warnings on tobacco products,[42 43] this feasible protocol holds promise for improving our ability to determine the utility of warnings on cigarette packages. Our recommended protocol developed through this proof of principle study mimics real-world exposure to tobacco product packaging while allowing

Table 4 Recommended pack labelling protocol for studies that place warnings on smokers' cigarette packs

Protocol step	Rationale
1. Schedule appointments weekly	A week is feasible for smokers who would purchase cigarettes for the study, and it limits the number of cigarette packs smokers have on hand
2. Determine cigarette consumption	Knowing how much a smoker typically smokes allows the researcher to instruct the smoker on how many packs to bring to the first and subsequent study visits
3. Ask smokers to purchase and bring cigarettes to study appointments	Asking smokers to purchase cigarettes on their own can help prevent smokers from thinking that the study is giving smokers 'free cigarettes.' Asking them to bring extra packs allows for a buffer against missed appointments or in case they smoke more than expected in a given week
4. Apply labels to smokers' cigarette packs	Researchers label the packs, rather than smokers self-labelling packs, as self-labelling may serve as an active intervention. Also, researchers labelling packs is likely to lead to higher protocol compliance as compared to asking smokers to self-label their packs
5. Provide participation incentives for survey completion	Communicating that study incentives are for survey completion may reduce the possibility that participants will perceive that payments equate to receiving free cigarettes
6. Refer smokers to cessation services at study completion	Referral to cessation services may help smokers to quit at the end of the study, if they have not already

for experimental control needed in randomised trials. The protocol could be used to test the impact of other cigarette pack warning characteristics such as size and format, as well as the impact of modified-risk tobacco product warnings.[44] [45] Moreover, researchers can adapt the protocol to test graphic or text warnings for non-cigarette tobacco products. Future research should examine the utility of our pack labelling protocol in randomised controlled trials.

Rigorous evidence is required to identify the best ways to communicate the risks of tobacco use, de-normalise tobacco products and reduce the extent to which tobacco product packaging glamorises and promotes the deadly product inside. Our proof of principle studies provide a feasible strategy for testing warning messages that ensures high adherence, and can generate stronger evidence of the real-world impact of warnings on smoking-related outcomes.

What this paper adds

- ► Experimental studies on graphic cigarette pack warnings typically use a brief one-time exposure, often in a laboratory setting.
- ► Naturalistic pack labelling studies hold promise for replicating the frequency and duration of warning exposure in the real world while maintaining experimental control.
- ► We developed and tested a six-step protocol for labelling smokers' actual cigarette packs. The protocol was feasible to implement, was acceptable to smokers, and had high retention over four weeks. Using the protocol can yield stronger evidence on the impact of warnings to better inform the development of cigarette pack warning policies around the world.

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Understanding Why Pictorial Cigarette Pack Warnings Increase Quit Attempts

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Abstract

Background Our randomized trial found that pictorial cigarette pack warnings elicited more quit attempts than text-only warnings.

Purpose In the current study, we sought to identify psychological mechanisms that explain why pictorial cigarette pack warnings change behavior.

Methods In 2014 and 2015, we recruited 2,149 adult smokers in NC and CA, USA. We randomly assigned smokers to receive on their cigarette packs for 4 weeks either a text-only warning (one of the USA's current warnings on the side of cigarette packs) or a pictorial warning (one of the USA's proposed text warnings with pictures on the top half of the front and back of cigarette packs).

Results Pictorial warnings increased attention to, reactions to, and social interactions about cigarette pack warnings (all $p < .05$). However, pictorial warnings changed almost no belief or attitude measures. Mediators of the impact of pictorial warnings included increased attention, negative affect, social interactions, thinking about the warning and harms of smoking, and intentions to quit (all $p < .05$). Analyses also found that pictorial warnings led to greater avoidance of the warnings, which was associated with more quit attempts ($p < .05$).

Conclusions Pictorial warnings increased quit attempts by eliciting aversive reactions and by keeping the message vividly in smokers' minds. Contrary to predictions from several theories of health behavior, the warnings exerted little of their influence through changes in beliefs and attitudes and none of their influence through changes in risk perception. We propose the Tobacco Warnings Model based on these findings.

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Keywords pictorial warnings • cigarettes • smoking • quit attempts • mediation analysis • randomized controlled trial

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Introduction

Tobacco is the leading cause of preventable death worldwide, accounting for nearly 6 million deaths per year mostly due to cancer and cardiovascular disease [1]. Pictorial cigarette pack warnings are a promising solution for curbing the tobacco epidemic. More than 100 countries, with nearly 60% of the world's population, have policies that require pictorial warnings on cigarette packs [2]. A systematic review [3] and a large randomized

clinical trial [4] demonstrate that pictorial cigarette pack warnings promote cessation behavior, including quit attempts, across a wide range of samples and cultural contexts.

The psychological mechanisms through which pictorial warnings change behavior are largely unknown, although health behavior theories and empirical models have identified many possibilities [3, 5–8]. The Elaboration Likelihood Model [9] suggests that pictorial warnings could increase attention [10–13] and cognitive elaboration (e.g., thinking about the warning and harms of smoking) [14–17], which should lead to persuasion (i.e., attitude change [18, 19]) and then behavior change. Expectancy value theories—including the Health Belief Model [20], the Theory of Planned Behavior [21], and the Tripartite Model of Risk Perceptions [22]—suggest that pictorial warnings could exert their effects by changing risk perceptions and attitudes. The Extended Parallel Process Model [23] suggests that pictorial warnings may change behavior by eliciting fear [24–27] and adaptive responding, or they may instead elicit maladaptive coping in the form of message reactance and avoidance to dispel fear [28–33]. These psychological mechanisms share the insight that pictorial warnings generate deeper engagement with the messages.

To establish which of these mechanisms has empirical support, researchers can measure the candidate constructs and use mediation analyses. Several researchers have done this work using observational study data or non-behavioral outcomes [14, 34, 35]. Our study contributes by examining a comprehensive set of mediators in a single prospective, randomized clinical trial with a behavioral endpoint. Thus, our study aimed to identify psychological mechanisms that explain why pictorial cigarette pack warnings increase quit attempts. Understanding these mechanisms will help tobacco control programs design better warnings and will advance a deeper understanding of why pictorial cigarette pack warnings change behavior.

Methods

Study Design and Population

We used longitudinal data from a randomized clinical trial with 2,149 adult smokers living in North Carolina and California. Details of the trial including study protocols, questionnaire development, and participant recruitment have been previously published [4]. Other papers using this dataset have explored the frequency and content of social interactions [36], reactance to warnings [37], and trajectories of pictorial warnings' impact [38], as well as attitudes toward regulation of tobacco products [39, 40]. From September 2014 to August 2015, we recruited English-speaking current smokers over the age of 18 to participate in the trial (see Table 1 for participant characteristics). Smokers brought in an eight-day supply of

Table 1 Participant characteristics (N = 2,149)

	n	(%)
Demographics		
Study site		
California	1,186	(55.2)
North Carolina	963	(44.8)
Age		
18–24 years	323	(15.3)
25–39 years	775	(36.7)
40–54 years	642	(30.4)
≥55 years	371	(17.6)
Mean (SD)	39.7	(13.5)
Gender		
Male	1,039	(48.7)
Female	1,060	(49.7)
Transgender	34	(1.6)
Gay, lesbian, or bisexual	368	(17.5)
Hispanic	181	(8.6)
Race		
American Indian or Alaska Native	18	(0.9)
Asian	70	(3.3)
Black or African American	994	(47.3)
Native Hawaiian or other Pacific Islander	17	(0.8)
White	751	(35.7)
Other/multiracial	251	(11.9)
Education		
High school graduate or less	677	(31.8)
Some college	1,021	(47.9)
College graduate	312	(14.6)
Graduate degree	121	(5.7)
Household income, annual		
$0–$24,999	1,155	(54.5)
$25,000–$49,999	538	(25.4)
$50,000–$74,999	202	(9.5)
≥$75,000	224	(10.6)
Low income (≤150% of federal poverty level)		
No	983	(45.9)
Yes	1,159	(54.1)
Cigarettes smoked per day, mean (SD)	8.7	(7.0)
Smoking frequency		
Daily	1,730	(80.5)
Non-daily	418	(19.5)
Primary trial outcome at baseline		
Made quit attempt in last month	545	(26.5)

Study characteristics and outcomes at baseline did not differ by trial arm. Missing demographic data ranged from 0.7% to 2.2%. SD = standard deviation.

their own cigarettes weekly and received warnings on their packs for four weeks [4, 41]. Participants were randomly assigned to have one of four pictorial warnings applied to

Panel A. Pictorial warnings used in experiment

Panel B. Text-only warnings used in experiment

SURGEON GENERAL'S WARNING:
Smoking Causes Lung Cancer, Heart Disease,
Emphysema, and May Complicate Pregnancy.

SURGEON GENERAL'S WARNING:
Smoking by Pregnant Women May Result
in Fetal Injury, Premature Birth, and
Low Birth Weight.

SURGEON GENERAL'S WARNING:
Quitting Smoking Now Greatly Reduces
Serious Risks to Your Health.

SURGEON GENERAL'S WARNING:
Cigarette Smoke Contains
Carbon Monoxide.

Fig. 1. Warnings used in the trial

the top half of the front and back panels of their cigarette packs (Fig. 1), or one of four text-only warnings applied to the side of their cigarette packs placed over the current Surgeon General's warning, for the duration of the study. Randomization created arms that did not differ on key demographic characteristics (all $p > .05$) [4]. Participants completed two computer surveys at the first study visit (i.e., baseline and immediately after seeing their assigned warning) and one survey at each visit thereafter. Participants provided written informed consent before enrollment. The University of North Carolina Institutional Review Board approved the study procedures.

Measures

The primary trial outcome was attempting to quit smoking during the study. At each of the follow-up visits, smokers answered the following survey question: "During the last week, did you stop smoking for 1 day or longer because you were trying to quit smoking?" The survey at Week 4 follow-up also asked, "Since you started the study, did you stop smoking for 1 day or longer because you were trying to quit smoking?" We

considered participants to have made a quit attempt if they answered "yes" to any of the quit attempt questions.

Surveys assessed psychological constructs from all stages of the Message Impact Framework to serve as potential mediators (see Supplementary Material 1) [8]. The categories of variables were attention/noticing, warning reactions, social interactions, attitudes and beliefs, intentions to quit smoking, and perceived effectiveness of the warnings (see Table 2 for a full list of variables and measurement time points). Cronbach's alpha was .70 or greater for all multi-item scales, except for two reactance subscales (discounting and government), which were both greater than .60.

Statistical Analysis

Analyses used an intent-to-treat approach, including all participants randomized in the trial, using the last observation available for missing data [42]. First, we compared trial arms on each potential mediator at each time point using t-tests. We characterized the associations using Cohen's d, calculated using PROC TTEST in SAS v9.4 (SAS Institute Inc., Cary, NC). To facilitate use of our findings in future meta-analyses as well as interpretation of the relative size

Table 2 Effects of pictorial warnings on mediators (N = 2,149)

Mediator (# of items)	Week 0 d (95% CI)	Week 1 d (95% CI)	Week 2 d (95% CI)	Week 3 d (95% CI)	Week 4 d (95% CI)
Attention/noticing (3)	—	10.02 (0.92, 10.11)*	0.82 (0.73, 0.91)*	0.74 (0.64, 0.83)*	0.82 (0.73, 0.91)*
Warning reactions					
Cognitive elaboration (4)	—	0.44 (0.35, 0.53)*	0.38 (0.29, 0.47)*	0.38 (0.29, 0.47)*	0.38 (0.30, 0.47)*
Thinking about the warning message (2)	—	0.63 (0.54, 0.73)*	0.56 (0.47, 0.65)*	0.56 (0.47, 0.65)*	0.55 (0.46, 0.64)*
Thinking about the harms of smoking (2)	—	0.14 (0.05, 0.23)*	0.11 (0.02, 0.20)*	0.10 (0.02, 0.19)*	0.12 (0.04, 0.21)*
Negative affect (15)	0.85 (0.76, 0.94)*	0.76 (0.67, 0.84)*	0.66 (0.57, 0.75)*	0.63 (0.55, 0.72)*	0.59 (0.51, 0.68)*
Anxiety (3)	0.84 (0.75, 0.93)*	0.72 (0.63, 0.80)*	0.64 (0.56, 0.73)*	0.60 (0.51, 0.69)*	0.56 (0.48, 0.65)*
Disgust (3)	10.04 (0.95, 10.13)*	0.92 (0.83, 10.01)*	0.81 (0.72, 0.89)*	0.75 (0.66, 0.84)*	0.75 (0.66, 0.84)*
Fear (3)	0.71 (0.63, 0.80)*	0.64 (0.56, 0.73)*	0.58 (0.50, 0.67)*	0.56 (0.48, 0.65)*	0.52 (0.44, 0.61)*
Guilt (3)	0.59 (0.51, 0.68)*	0.56 (0.48, 0.65)*	0.50 (0.42, 0.59)*	0.50 (0.41, 0.59)*	0.46 (0.38, 0.55)*
Sadness (3)	0.72 (0.63, 0.80)*	0.61 (0.53, 0.70)*	0.52 (0.43, 0.60)*	0.54 (0.45, 0.62)*	0.46 (0.37, 0.54)*
Negative cigarette pack attitudes (6)	—	—	—	—	0.49 (0.40, 0.58)*
Perceived understandability (1)	0.10 (0.01, 0.18)*	—	—	—	0.10 (0.02, 0.19)*
Reactance, brief form (3)	0.44 (0.35, 0.52)*	0.38 (0.29, 0.46)*	—	—	0.30 (0.21, 0.38)*
Reactance, long form subscales			—	—	
Anger (3)	0.46 (0.37, 0.55)*	0.40 (0.32, 0.49)*	—	—	0.32 (0.24, 0.41)*
Common knowledge (3)	−0.25 (−0.34, −0.17)*	−0.16 (−0.24, −0.07)*	—	—	−0.13 (−0.22, −0.05)*
Derogation (3)	−0.10 (−0.19, −0.02)*	−0.11 (−0.20, −0.03)*	—	—	−0.11 (−0.19, −0.02)*
Discounting (3)	0.32 (0.23, 0.40)*	0.25 (0.17, 0.34)*	—	—	0.22 (0.14, 0.31)*
Exaggeration (3)	0.29 (0.21, 0.38)*	0.23 (0.15, 0.32)*	—	—	0.20 (0.11, 0.28)*
Government (3)	0.32 (0.24, 0.41)*	0.25 (0.17, 0.34)*	—	—	0.20 (0.11, 0.28)*
Manipulation (3)	0.41 (0.33, 0.50)*	0.36 (0.28, 0.45)*	—	—	0.29 (0.21, 0.38)*
Personal attack (3)	0.37 (0.28, 0.45)*	0.33 (0.24, 0.41)*	—	—	0.31 (0.22, 0.39)*
Self-relevance (3)	0.06 (−0.03, 0.14)	0.04 (−0.04, 0.13)	—	—	0.02 (−0.06, 0.11)
Warning avoidance (3)	—	0.75 (0.65, 0.84)*	0.61 (0.51, 0.70)*	0.59 (0.50, 0.68)*	0.56 (0.47, 0.65)*
Worry about consequences of smoking (4)	0.09 (0.00, 0.17)*	0.08 (−0.00, 0.17)	0.09 (0.00, 0.17)*	0.07 (−0.02, 0.15)	0.08 (−0.00, 0.17)
Social interactions (3)	—	0.41 (0.32, 0.49)*	0.28 (0.19, 0.36)*	0.21 (0.12, 0.29)*	0.21 (0.12, 0.29)*
Attitudes and beliefs					
Anticipated regret of quitting smoking (3)	—	—	−0.08 (−0.16, 0.01)	—	−0.05 (−0.13, 0.04)
Anticipated regret of smoking (3)	—	—	−0.11 (−0.19, −0.02)*	—	−0.08 (−0.17, 0.00)
Negative consequences of smoking (4)	0.00 (−0.08, 0.09)	−0.01 (−0.09, 0.08)	0.03 (−0.05, 0.12)	0.04 (−0.05, 0.12)	0.02 (−0.07, 0.10)
Perceived benefits of quitting smoking (4)	—	−0.02 (−0.10, 0.07)	0.04 (−0.05, 0.12)	0.01 (−0.08, 0.09)	0.03 (−0.05, 0.12)
Perceived costs of quitting smoking (4)	—	−0.07 (−0.15, 0.02)	−0.02 (−0.10, 0.07)	−0.02 (−0.10, 0.07)	−0.01 (−0.08, 0.09)
Perceived likelihood of harm from smoking (3)	—	—	0.04 (−0.04, 0.13)	—	0.03 (−0.05, 0.11)

Table 2 Continued

Mediator (# of items)	Week 0 d (95% CI)	Week 1 d (95% CI)	Week 2 d (95% CI)	Week 3 d (95% CI)	Week 4 d (95% CI)
Perceived severity of harm from smoking (3)	—	—	0.00 (−0.09, 0.08)	—	−0.01 (−0.10, 0.07)
Perceived threat (PL*PS)	—	—	0.04 (−0.05, 0.14)	—	0.02 (−0.07, 0.11)
Perceived severity of negative consequences of quitting smoking (3)	—	—	0.00 (−0.09, 0.08)	—	−0.01 (−0.09, 0.08)
Perceived efficacy (8)	—	—	0.12 (0.03, 0.22)*	—	0.11 (0.02, 0.20)*
Self-efficacy to quit smoking (5)	—	—	0.10 (0.02, 0.19)*	—	0.12 (0.03, 0.20)*
Response efficacy of quitting smoking: lower risk of health problems (3)	—	—	0.05 (−0.04, 0.13)	—	0.03 (−0.05, −0.12)*
Perceived efficacy*Threat	—	—	0.09 (−0.01, 0.18)	—	0.07 (−0.02, 0.16)
Response efficacy of quitting smoking: cause negative consequences (3)	—	—	−0.03 (−0.12, 0.05)	—	−0.01 (−0.09, 0.08)
Smoker prototypes (8)	0.03 (−0.06, 0.11)	0.03 (−0.05, 0.12)	0.00 (−0.09, 0.08)	−0.01 (−0.09, 0.08)	−0.08 (−0.16, 0.01)
Negative (4)	0.05 (−0.03, 0.13)	0.05 (−0.03, 0.14)	0.09 (0.01, 0.18)*	0.10 (0.01, 0.18)*	0.16 (0.08, 0.25)*
Positive (4)	0.10 (0.01, 0.18)*	0.11 (0.02, 0.19)*	0.11 (0.03, 0.20)*	0.11 (0.02, 0.19)*	0.09 (0.01, 0.17)*
Smoking reinforcement attitudes – negative (4)	−0.03 (−0.11, 0.06)	−0.06 (−0.14, 0.03)	−0.04 (−0.120. 0.05)	−0.01 (−0.09, 0.08)	−0.03 (−0.12, 0.05)
Smoking reinforcement attitudes – positive (4)	0.02 (−0.07, 0.10)	0.01 (−0.08, 0.09)	−0.01 (−0.09, 0.08)	0.00 (−0.09, 0.08)	−0.02 (−0.10, 0.07)
Subjective norms of quitting smoking (4)	—	−0.02 (−0.10, 0.07)	0.01 (−0.08, 0.09)	0.02 (−0.06, 0.11)	−0.01 (−0.10, 0.07)
Intentions					
Quit intentions (3)	0.26 (0.18, 0.35)*	0.19 (0.10, 0.27)*	0.20 (0.11, 0.28)*	0.15 (0.07, 0.24)*	0.16 (0.07, 0.24)*
Quit stage (1)	0.15 (0.07, 0.24)*	0.13 (0.05, 0.22)*	0.14 (0.05, 0.22)*	0.11 (0.03, 0.20)*	0.14 (0.05, 0.22)*
Perceived effectiveness of warnings (3)	0.71 (0.63, 0.80)*	—	—	—	—

Table reports Cohen's *d*, which is the difference between intervention and control, divided by the pooled standard deviation. Intent-to-treat analyses included all participants randomized. Sample sizes after carrying the last value forward range from 2,122 to 2,149 at Week 0, 1,821 to 2,149 at Week 1, 1,908 to 2,149 at Week 2, 1,930 to 2,149 at Week 3, and 1,997 to 2,149 at Week 4. Week 0 refers to survey at first visit, immediately after smokers saw their labeled cigarette packs. CI = confidence interval. — = not assessed. * designates an interaction term. Numbers in parentheses indicate the number of items in the scale. PL*PS = perceived likelihood * perceived severity.

*$p < .05$

of the effects, we report the effect sizes (Cohen's d) for scales and subscales at all times we had data available.

Second, we conducted mediation analyses to identify variables that could explain the association between pictorial warnings and quit attempts (i.e., mediation). We characterized associations using standardized regression coefficients (β). The MacKinnon approach [43] to mediation is to (a) examine the association of trial arm to mediator (a pathway), (b) examine the association of mediator to quit attempt outcome, adjusting for trial arm (b pathway), and (c) examine the product of the two ($a*b$ pathway) (Fig. 2). Mediation exists if $\beta_a*\beta_b$ is larger or smaller than 0. Mediation analyses used a separate structural equation model for each potential mediator, at the earliest observation available, in M$plus$ version 7.4 (Muthén & Muthén, Los Angeles, CA). We parceled the mediator variables in the model based on theoretical grounds, high correlations between items, and to simplify model specification [44]. To allow use of the full sample, analyses accounted for missing data by employing full information maximum likelihood estimation available in M$plus$. Mediation analyses used bootstrapped 95% confidence intervals with 1,000 repetitions, as this approach does not assume that indirect effects are normally distributed [45]. All models had acceptable fit statistics (CFI > 0.95 and RMSEA < 0.05).

Finally, based on our findings, we identified the most active variables in the Message Impact Framework to create a parsimonious empirical model of the process through which warnings exert their influence. The model included variables that had relatively large mediated pathways (statistically significant and larger than .02) and that did not assess conceptually similar constructs (e.g., we did not include intentions and perceived message effectiveness). We evaluated the model using structural equation modeling, using the same methods described above.

Results

Attention to the warnings was greater for pictorial than text warnings at all four of the follow-up time points it was measured (median d = .82, all p < .05, Table 2). Pictorial warnings elicited stronger effects at all time points for most of the eight warning reactions measures (median d = .43, most p < .05). The exceptions were worry, which showed differences at two of the five time points, the reactance self-relevance subscale, which showed no difference at any time point, and the common knowledge and derogation reactance subscales, which
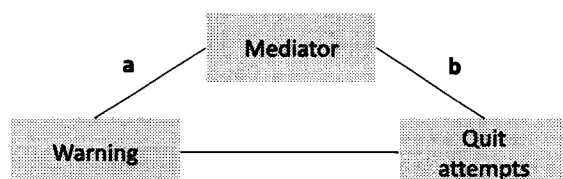

Fig. 2. Mediation model

were higher in the text arm. Among warning reactions, the largest effect size was for the disgust subscale of negative affect (median d = .81, all p < .05). Pictorial warnings led to more social interactions about the warnings at all follow-up time points (median d = .25, all p < .05). However, pictorial warnings affected only two of the 18 belief and attitude measures (median d = .03, few p < .05). Belief and attitude constructs affected in at least two time points were self-efficacy and positive and negative prototypes. Finally, pictorial warnings led to higher intentions (median d = .15, all p < .05) and perceived message effectiveness (d = .71, p < .05) at all time points measured.

The two largest mediation effects were for attention/noticing and thinking about the warnings (both $\beta_a*\beta_b$ = .15, p < .05), in simple mediation analyses (Table 3). Other larger mediation effects were for avoidance, perceived effectiveness, negative affect, and negative cigarette pack attitudes ($\beta_a*\beta_b$ = .12, .11, .09 and .07, p < .05). Constructs with smaller path coefficients were quit intentions, self-efficacy, social interactions, worry, self-efficacy, and quit stage. Reactance suppressed the impact of pictorial warnings, although this effect was one of the smallest we identified ($\beta_a*\beta_b$ = −.02, p < .05).

Based on our findings, we built the Tobacco Warnings Model, shown in Fig. 3. The model showed acceptable fit: χ^2 [13] = 172, p < .001; RMSEA = .076 (90% CI: .066 to .086); CFI = .934. When respecifying the model, we added a correlation between attention and quit intentions to account for the theoretical supposition that people intending to quit pay more attention to the warnings (Supplementary Fig. 4). The revised model showed good fit: χ^2 [12] = 118, p < .001; RMSEA = .064 (90% CI: .054 to .075); CFI = .956. All pathways in the models were statistically significant, (p < .05).

Discussion

Pictorial warnings on cigarette packs increase quit attempts and quitting [3, 4], but why they do so is poorly understood. This large gap hampers cancer and cardiovascular disease prevention efforts that focus on smoking. Our large trial with U.S. smokers showed that pictorial warnings increased quit attempts by eliciting aversive reactions and by keeping the message vividly in smokers' minds. The warnings exerted little of their influence through changes in beliefs and attitudes and none of their influence through changes in risk perception. Given the emphasis in past research on these factors in eliciting behavior change, this pattern of findings was unexpected. Pictorial warnings kept the risk messages in people's minds without increasing perceived risk. They increased negative affect and anger (a part of reactance [28, 46, 47]), yet negative affect motivated quit attempts even as anger had the opposite effects. They increased social interactions but not subjective norms. They increased avoidance of the warning, which was associated with *more* quit attempts.

Table 3 Mediation of pictorial warnings' effect on quit attempts, single mediator analyses ($N = 2,149$)

Mediator	Week	a pathway β_a	b pathway β_b	$a*b$ pathway $\beta_a*\beta_b$
Attention/noticing	1	.45*	.32*	.15*
Warning reactions				
Cognitive elaboration	1	.22*	.37*	.08*
Thinking about the warning message	1	.30*	.38*	.12*
Thinking about the harms of smoking	1	.07*	.27*	.02*
Negative affect	0	.39*	.23*	.09*
Anxiety	0	.39*	.20*	.08*
Disgust	0	.46*	.20*	.09*
Fear	0	.34*	.23*	.08*
Guilt	0	.29*	.22*	.06*
Sadness	0	.34*	.21*	.07*
Negative cigarette pack attitudes	4	.24*	.27*	.07*
Perceived understandability	0	.05*	−.05	.00
Reactance, brief form	0	.21*	−.07*	−.02*
Reactance, long form subscales				
Anger	0	.22*	−.04	−.01
Common knowledge	0	−.13*	−.15*	.02*
Derogation	0	−.05*	−.09*	.00
Discounting	0	.16*	.03	.00
Exaggeration	0	.14*	.00	.00
Government	0	.16*	−.09*	−.01*
Manipulation	0	.20*	−.07*	−.01*
Personal attack	0	.18*	−.01	.00
Self-relevance	0	.03	−.01	.00
Warning avoidance	1	.35*	.34*	.12*
Worry about consequences of smoking	0	.04*	.24*	.01*
Social interactions	1	.20*	.19*	.04*
Attitudes and beliefs				
Anticipated regret of quitting smoking	2	−.04	−.22*	.01
Anticipated regret of smoking	2	−.05*	.03	.00
Negative consequences of smoking	0	.00	.03	.00
Perceived benefits of quitting smoking	1	−.01	−.02	.00
Perceived costs of quitting smoking	1	−.04	−.21*	.01
Perceived likelihood of harm from smoking	2	.02	.10*	.00
Perceived severity of harm from smoking	2	.00	−.05*	.00
Perceived threat (PL*PS)	2	.02	.08*	.00
Perceived severity of negative consequences of quitting smoking	2	.00	−.12*	.00
Perceived efficacy	2	.06*	.34*	.02*
Self-efficacy to quit smoking	2	.05*	.37*	.02*
Response efficacy of quitting smoking: lower risk of health problems	2	.02	.10*	.00
Perceived efficacy*Perceived threat	2	.04	.21*	.01
Response efficacy of quitting smoking: cause negative consequences	2	−.02	−.15*	.00
Smoker prototypes	0	.01	−.10*	.00
Negative	0	.03	.12*	.00
Positive	0	.05*	.01	.00
Smoking reinforcement attitudes—negative	0	−.01	−.15*	.00
Smoking reinforcement attitudes—positive	0	.01	−.17*	.00

Table 3 Continued

Mediator	Week	a pathway β_a	b pathway β_b	a*b pathway $\beta_a * \beta_b$
Subjective norms of quitting smoking	1	−.01	.12*	.00
Intentions				
Quit intentions	0	.13*	.39*	.05*
Quit stage	0	.08*	.32*	.02*
Perceived effectiveness of warnings	0	.34*	.32*	.11*

Outcome variable was having reported a quit attempt during the 4-week trial. Table reports β, the standardized path coefficient. Analyses used a single mediator. Week 0 refers to survey at first visit, immediately after smokers saw their labeled cigarette packs. To allow use of the full sample, analyses accounted for missingness by employing full information maximum likelihood estimation available in M*plus*.
* designates an interaction term. PL*PS = perceived likelihood * perceived severity.

*$p < .05$
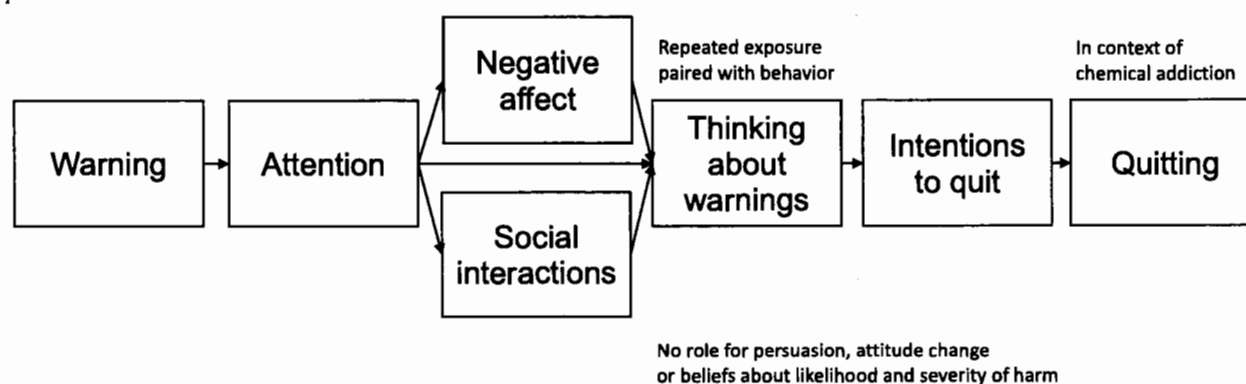
Fig. 3. Tobacco Warnings Model

Taken together, these findings do not conform to existing models of health behavior. To come to this conclusion, we compared our findings with the predictions of six widely used health behavior change theories in the first three columns of Table 4. As additional background on pictorial warnings, the table also includes findings on the warning-to-mediator pathways (*a*) from our trial [4], a meta-analysis of experiments [8], and systematic reviews of the impact of warning policy change as documented in observational studies [3, 5]. One of the oldest and most widely used theories, the Health Belief Model [20], did not fit our findings. Support was modest at best for the Theory of Planned Behavior [21], mostly due to the lack of impact that the warnings had on behavioral attitudes, which are a central construct in the model. Support was modest for the Elaboration Likelihood Model [9]; its central pathway to persuasion through attitude change was not well supported but other aspects of the model related to gaining people's attention and increasing cognitive elaboration garnered some support. Finally, the Extended Parallel Process Model [23], which was specifically designed to understand fear communication, had modest support. The risk predictions failed [8, 34, 35, 48], but the pathways through fear (and other negative emotions) received clear support. An important

shortcoming of the Extended Parallel Process Model in this context is that warning avoidance—in the model as a defensive reaction—acted as a marker for motivation to quit, not an undermining factor. Similarly, several observational studies have found that avoidance does not hinder smoking cessation [31, 32] and may in fact be associated with *more* quit attempts [33].

We make several other observations that can inform future theorizing and may explain the existing theories' limitations in accounting for pictorial warnings' effects. First, smoking is a special type of health behavior in that it involves addiction to nicotine. If smokers cannot change their behavior, they may shift their beliefs or attitudes to be consistent with the undesired behavior, and these beliefs and attitudes may change only after the smoker has successfully quit [49]. It is worth noting that while smokers' attitude toward the *pack* was a mediator of quit attempts, attitudes and beliefs about the act of *smoking* were not, and our data suggest these do not change in response to pictorial warnings. Similarly, smokers routinely underestimate their health risks relative to nonsmokers, and the general idea that smoking is a harmful behavior is familiar to many smokers [50, 51]. It is also true that warnings typically address severity but not the likelihood of disease. Also, repeated exposures to

Table 4 Support for theories of health behavior

	Analysis of support		Additional information		
	Support for theory	Findings from RCT a*b pathway	Findings from RCT a pathway	Meta-analysis of experiments [8] a pathway	Systematic reviews of observational studies [3, 5] a pathway
Theory					
Construct (measure in RCT)					
Health Belief Model [20]	No support				
Perceived likelihood		O	O	O	O
Perceived severity		O	O	●1	●1
Perceived threat (PL*PS)		O	O	—	—
Perceived benefit of quitting		O	O	—	—
Perceived costs of quitting		O	O	—	—
Transtheoretical Model [52]	Modest support				
Perceived benefits (pros of quitting)		O	O	—	—
Perceived costs (cons of quitting)		O	O	—	—
Processes of change		—	—	—	—
Self efficacy		●	●	O	—
Stage of change (quit stage)		●	●	—	—
Theory of Planned Behavior [21]	Modest support				
Attitudes (attitudes toward smoking)		O	O	●	●1
Subjective norms		O	O	—	—
Perceived behavioral control (SE+RE)		●	●	OSE	—
Intentions (quit intentions)		●	●	●	◎
Constructs added to theory	No support				
Anticipated regret		O	O	—	—
Smoker prototypes		O	◎	—	—
Behavioral willingness		—	—	—	—
Tripartite Model of Risk Perceptions [22]	Modest support				
Deliberative risk (perceived likelihood)		O	O	O	O
Affective risk (negative affect)		●	●	●	◎ 1
Experiential risk		—	—	—	—
Elaboration Likelihood Model (9)					
Attention/noticing	Modest support	●	●	●	●
Recall/recognition		—	—	●	◎
Perceived understandability		O	●	—	—
Cognitive processing (cognitive elaboration)		●	●	●	●
Attitude change		O	O	●	●
Extended Parallel Process Model [23]	Modest support				
Perceived threat (PL*PS)		O	O	—	—
Perceived efficacy (SE+RE)		●	●	OSE	—
Perceived threat*Perceived efficacy		O	O	— ·	—
Protection motivation (quit intentions)		●	●	●	◎
Fear (negative affect)		●	●	●	◎ 1
Defensive motivation (reactance)		●	●	●	—
Maladaptive changes (avoidance)		O*	●	—	●

Analysis for support of the theory is based largely on the mediational findings from the trial (a*b pathway). O = no support for prediction. ◎ = mixed support for prediction. ●= support for prediction. — = mediator not assessed. 1 = based on only 1 study in the reviews. SE = self-efficacy. RE = response efficacy of quitting smoking to lower risk of health problems. *Path goes in the opposite direction predicted (prediction from theory: avoidance undermines effect of warnings; finding in RCT: avoidance reinforces/mediates impact of warnings). PL*PS = perceived likelihood * perceived severity.

the warnings are paired directly with the repeated behavior of smoking, allowing their effects to accumulate over time. Thus, even if warnings do not shift risk beliefs and smoking attitudes, the constant presence of the warnings on the packs may act as a risk reminder that counteracts smokers' active minimization of risk, and people motivated to quit by the warnings may increase their attention to the warnings.

Building on our trial findings and previous work including the Message Impact Framework [3–5, 8], we propose the Tobacco Warnings Model (Fig. 3) as a way to advance our theoretical understanding of why tobacco warnings exert their effects on behavior. The model proposes that tobacco product warnings increase noticing of and attention to the message. This processing leads to greater negative affect including fear and more conversations with other people about the warnings. Though smokers, most of whom are addicted to nicotine, will generally not change their risk perceptions, the repeated exposure to the warnings keeps the warnings on their mind. The next step is an increase in motivation to quit smoking, as evidenced by greater intentions to quit smoking. Finally, warnings will increase quit attempts and quitting. The model focuses on mediators shown to be important in our trial and other studies. However, future studies should confirm the model given the post hoc nature of our proposal. A strength of the model is its parsimony, but additional constructs such as message reactance, avoidance, and pack attitudes may also play small but important roles [33].

Study strengths include a large and diverse sample, a successful trial with respect to the primary trial outcome of behavior, and a large number of potential mediators. Study limitations include the imperfect comparison of existing text warnings with the novel text of the pictorial warnings. For this reason, the trial did not have an adequate assessment of message recall, another potential mediator. The trial also did not assess knowledge, which may be especially relevant to policymakers, but knowledge is rarely a motivator of behavior change. The trial provided data for people's responses in the weeks after first exposure, but the generalizability to responses over the longer term remains to be established. As warnings wear out over time, the relative strength of the pathways may change. Finally, as this trial was in a country with text-only warnings currently on cigarette packs, the generalizability of the findings will need to be established for countries that have already adopted pictorial warnings.

Future studies should examine whether warnings designed to target the Tobacco Warnings Model's five core constructs (attention, negative affect, social interactions, thinking about the warnings, and motivation) are more effective than those targeting other potential mediators. Pictorial cigarette warning studies have yet to examine some additional relevant constructs, including

experiential perceived risk (e.g., feeling concerned about harms of smoking) [22]. Studies could also examine the value of the Tobacco Warnings Model in other cancer prevention contexts. The model may be helpful for understanding the impact of warnings on other tobacco products such as e-cigarettes, cigarillos, and hookah, and warnings to reduce other behaviors that contribute to obesity such as consumption of sugar-sweetened beverages and unhealthy snack foods.

Supplementary Material

Supplementary material is available at *Annals of Behavioral Medicine* online.

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Effects of Varying Color, Imagery, and Text of Cigarette Package Warning Labels among Socioeconomically Disadvantaged Middle School Youth and Adult Smokers

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ABSTRACT

The U.S. Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) of 2009 paved the way for the Food and Drug Administration (FDA) to propose nine different graphic warning labels (GWLs) intended for prominent placement on the front and back of cigarette packs and on cigarette advertisements. Those GWLs were adjudicated as unconstitutional on the ground that they unnecessarily infringed tobacco companies' free speech without sufficiently advancing the government's public health interests. This study examines whether less extensive alternatives to the original full-color GWLs, including black-and-white GWLs and text-only options, have similar or divergent effects on visual attention, negative affect, and health risk beliefs. We used a mobile media research lab to conduct a randomized experiment with two populations residing in socioeconomically disadvantaged communities: biochemically confirmed adult smokers (N = 313) and middle school youth (N = 340). Results indicate that full-color GWLs capture attention for longer than black-and-white GWLs among both youth and adult smokers. Among adults, packages with GWLs (in either color or black-and-white) engendered more negative affect than those with text-only labels, while text-only produced greater negative affect than the packages with brand imagery only. Among youth, GWLs and text-only labels produced comparable levels of negative affect, albeit more so than brand imagery. We thus offer mixed findings related to the claim that a less extensive alternative could satisfy the government's compelling public health interest to reduce cigarette smoking rates.

The 2009 U.S. Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) sought to inform Americans of the health risks of smoking, prevent uptake of cigarette smoking in youth, and lower smoking rates among adults. The Act paved the way for the Food and Drug Administration (FDA) to propose nine different GWLs intended for prominent placement on the front and back of cigarette packs and on cigarette advertisements. Major tobacco companies (TCs) took to court several concerns about the proposed graphic warning labels, arguing that the labels were both too extensive and ineffective in raising awareness of health risks associated with smoking. After a federal appeals court ruled in favor of these TCs, the FDA decided against pursuing further review in the Supreme Court, opting instead to revisit the content of the labels. To date, the FDA has not yet proposed new warnings.

Using eye-tracking technology and self-reported reactions to cigarette packs with varied warning labels, this study examines the TCs claim that a less extensive regulation, such as a warning with black-and-white (B&W) image or featuring only text, could satisfy the government's public health interest of reducing smoking rates. We focus on two populations from disadvantaged socioeconomic settings: biochemically confirmed adult smokers

and middle school youth. Smoking rates are higher among those living below the poverty level (26%) compared to those at or above it (14%; Centers for Disease Control and Prevention, 2016). In addition, 3,200 people try their first cigarette each day, and 9 of 10 people who become regular smokers try their first cigarette by age 18 (US Department of Health and Human Services (USDHHS), 2012). These populations share disproportionate burdens of tobacco use and are underrepresented in tobacco research.

Legal precedent and competing arguments

The U.S. Congress delegated regulatory authority over tobacco products to the FDA when it enacted the Tobacco Control Act in 2009 (H.R. 1256). The Tobacco Control Act specified that the FDA "shall issue regulations that require color graphics depicting the negative health consequences of smoking" (H.R. 1256, Division A, Title 2, Sec. 201(d)), specifying that the warnings would be in full color and cover the top 50% of both sides of cigarette boxes.

In 2011, the FDA released a set of nine warnings, following the presentation of draft warnings and a period of public comment. Major TCs immediately objected to the new warnings, arguing the

warnings extensively infringed on their right to market a legal product, specifically taking issue with the presence of a full-color image on the warning (in R.J. Reynolds Tobacco Company et al. vs. United States Food and Drug Administration, 2011). Drawing on the Central Hudson test (Central Hudson Gas & Electric Corp. vs. Public Service Commission, 1980), TCs argued that any warning requirement should be no more extensive than necessary to achieve the government's interest, implying that the proposed warnings were too extensive.

In 2012, the TCs won the case in the trial and appeals courts, and the U.S. government decided to reassess the labels rather than seek further legal review in the Supreme Court. The FDA remains under pressure to release new labels. In October 2016, the American Academy of Pediatrics and seven other medical and public health groups filed suit against the FDA, claiming that the number of smokers in the United States could have been reduced by millions in the time the FDA has taken to review the labels (Jenco, 2016). This underscores the need for communication researchers, policy analysts, and legal scholars to provide additional insights about the content and effectiveness of various warning label options that might satisfy the compelling government interest test while maintaining free speech protections. That test requires the government to show that a challenged regulation is the least restrictive means of achieving a compelling interest.

The U.S. government and TCs can be expected to differ both on what constitutes a compelling government interest and the least restrictive means of advancing that interest. The FDA argues that text-only warnings do not attract and hold attention at the same level as warnings with images and that warnings with imagery serve to inform potential smokers of the risks associated with smoking as well as support intentions of smokers who may want to quit (75 Fed.Reg. 69,524, 2010). The argument implicitly contends that even if people understand the health risks of smoking cigarettes, they may need reminders to make those risks salient.

TCs focus their arguments on whether the labels increase knowledge by informing people of smoking's health risks. They claim the government lacks a compelling interest in informing people of health risks associated with smoking, because people already know that smoking is harmful. Therefore, new warning labels will fail to change knowledge of smoking risks (R.J. Reynolds Tobacco Company et al., vs. United States Food and Drug Administration, 2011, Document 18, p. 23). TCs further argue that people already overestimate the risks associated with smoking (Schneider, Gadinger, & Fischer, 2012) and that graphic warning labels are a government-imposed "emotionally charged anti-smoking message" (R.J. Reynolds Tobacco Company et al. vs. United States Food and Drug Administration, 2011, doc 18, p. 14).

Communication theory and smoking behaviors

The message impact framework (Noar et al., 2016b) provides a lens for understanding the factors contributing to warning label effects. Our study examines whether variations in the use of color and graphic imagery influence key predictors of smoking behavior, including (1) visual attention, (2) negative emotional reactions, (3) health risk beliefs, and (4) quit intentions (among adult smokers) or smoking susceptibility (among youth). We focus particular attention on the role of negative emotional reactions in this process.

The idea that GWLs are nothing more than a government-imposed "emotionally charged message" runs against much of what has been discovered in the fields of communication, marketing, and psychology. Decades of research has tested the effectiveness of arguments and peripheral cues in shaping the persuasiveness of strategic messages (O'Keefe, 2002) as well as the important role of emotion in information processing (Slovic, Finucane, Peters, & MacGregor, 2004). Side by side with factual text claims, many of the format elements at issue (e.g., size, color, and placement) function as cues to encourage attention to messages and feature emotional appeals (e.g., fear, guilt) to aid in deeper processing and motivation (Evans et al., 2015; Peters, Lipkus, & Diefenbach, 2006). To this end, some legal scholars agree that emotion and reason are connected processes and that therefore emotionally evocative messages are not inherently problematic for the U.S. government to compel, as long as the messages are not misleading or erroneous (Corbin, 2014; Tushnet, 2014). TCs also rely on cues and emotional appeals in their own marketing and packaging, understandably so because human beings rely on cues in the environment to sift through a bombardment of stimuli to determine what is appealing, status-enhancing, important, useful, or threatening (Slovic et al., 2004). Once a stimulus is attended to, emotion is a key component of information processing, memory, and decision making.

Evidence of cigarette package warning label effectiveness

Scientific consensus is building that improved warnings on the U. S. cigarette packs will likely function as intended. In two systematic reviews of dozens of studies, the authors concluded that strengthened warnings (i.e., improved text, implemented graphic warnings, or enhanced graphic warnings relative to weaker versions) increased several key variables that are the foundations of future behavioral change: attention to the warnings, recall of their key messages, negative affect, perceived effectiveness, knowledge about smoking, increased quit attempts, and decreased smoking prevalence (Noar et al., 2016a, 2016b). Brewer et al. (2016) recently reported results from a randomized clinical trial in which researchers added, each week, either (a) a pictorial warning label to the top half of the cigarette pack, or (b) the existing Surgeon General's warning label to the side of each cigarette pack. Smokers exposed to pictorial warnings had a 6% increase in quit attempts over those exposed to the text-only warning (40% vs. 34%). Pictorial warnings appeared to work by increasing warning-related thoughts, thoughts about smoking harms, and negative emotions.

Combined, the meta-analyses and controlled field trial make a compelling argument that graphic warning labels can increase quit-related knowledge, emotions, intentions, and behavior among adult smokers. It is yet unclear, however, whether less restrictive versions of these labels may have comparable effects, whether these effects transfer to youth, or whether smokers from socioeconomically disadvantaged communities respond differently to such warnings.

Graphic warnings and socioeconomic status

As noted above, rates of cigarette smoking in the United States vary by socioeconomic status. Although smoking rates have declined in the past several decades (Centers for Disease Control and Prevention, 2016), the rate of decline has not been evenly distributed. Only 7% of Americans with a college degree smoked in 2015, versus 24% of those without a high school diploma and 34% of those with a graduate equivalency diploma (GED) (Centers for Disease Control and Prevention, 2016).

Previous research suggests that graphic, novel, and emotional cues in warning messages about cigarette smoking may be particularly important for those with less education and at lower income levels, because they grab attention, are more memorable, are easier to process, stimulate more discussion, and are harder to ignore than textual arguments (Durkin, Brennan, & Wakefield, 2012; Ramanadan, Nagler, McLoud, Kohler, & Viswanath, 2017; Thrasher et al., 2012). Studies have yet to test, with a socioeconomically disadvantaged population, whether warnings with full-color images are more effective than black and white images and, similarly, whether an equally prominent text-only warning could promote similar levels of visual attention and negative affect as a warning with an image.

Graphic warnings and youth

Although cigarette smoking is declining among adolescents, an estimated 1 in 20 youth between the ages of 12–17 have smoked a cigarette in the last 30 days. Nearly half of adult smokers became regular, daily smokers before age 18 (USDHHS, 2012). Despite being a primary target of tobacco control efforts, youth have been featured far less frequently than adults in GWL research. Indeed, a review of observational studies found only 12% focused solely on youth or adolescents (Noar et al., 2016b). Still, the available evidence suggests that GWLs may be effective at reducing positive smoking beliefs and susceptibility to smoking among youth.

Early studies found that the existing Surgeon General's warning did not convey specific health concerns to youth, who were unable to accurately recall textual warnings in general (Fischer, Krugman, Fletcher, Fox, & Rojas, 1993). More recent studies show that the depth of processing for text-only labels is low (Moodie, MacKintosh, & Hammond, 2010). Cues such as graphic images can attract attention and evoke emotional reactions in youth who are otherwise unable or unmotivated to process health messages (Keys, Morant, & Stroman, 2009). Teens spend more time looking at pictorial warnings than text-only warnings (Peterson, Thomsen, Lindsay, & John, 2010), and gaze duration predicts recall for pictorial warnings but not text-only warnings. Youth perceive pictorial warnings on cigarette packs as more effective than text-only warnings (Vardavas, Connolly, Karamanolis, & Kafatos, 2009), particularly when they contain graphic disease depictions (Hammond et al., 2012).

Several studies have looked at reactions to the proposed FDA warnings. One found that youth perceive full-color (FC) versions of these warnings as more effective than those in B&W

(Hammond, Reid, Driezen, & Boudreau, 2013). Another study concluded that the proposed FDA warnings elicit strong negative emotions and cognition among both youth and adult smokers (Nonnemaker, Choiniere, Farrelly, Kamyab, & Davis, 2015). A third, brain imaging study found evidence that viewing the proposed warnings lowered smoking cravings among adolescent smokers (Do & Galván, 2014). None of these studies, however, have systematically compared the effects of graphic FC, graphic B&W, text-only labels of similar size conveying the exact same verbal content or the long-standing Surgeon General's Warnings (SGWs) on visual attention, negative affect, and health risk beliefs, or whether these effects manifest themselves among youth from socioeconomically disadvantaged communities, one of the primary goals of the current paper.

Methods

Because the U.S. government may not compel more speech than necessary to achieve its interests—here, the interest in public health—our studies compare how exposure to less extensive alternatives to the full-color graphic warnings proposed by the FDA influences specific outcomes proposed in the message impact framework. With these considerations, we offer two randomized experiments with two different, socioeconomically disadvantaged populations named as key considerations in the Tobacco Control Act: adult smokers and middle-school youth. We manipulate features of the messages that TC's argued compelled speech beyond the point of public health benefits, particularly the use of a full-color image in addition to new text, holding the size (50% of the package) and placement of the warning (the top half) constant to avoid confounding the impact of warning label content features with size). The Institutional Review Board (IRB) of the authors' institution approved all study protocols and procedures.

Recruitment procedures and study participants

Adults
Adult participants (N = 313) resided in both rural and urban areas of the Northeastern United States. We identified low SES communities by a combination of analysis of median annual household income census data with attention to areas under $35K, contact with site-specific organizations that served low-SES communities, discussions with local representatives, and in-person site scouting. We visited each site only once, unless it was a large urban area, in which case up to three different parts of a given city served as data collection sites.

We first secured permits and necessary security in each community and, when possible, formed partnerships that met University IRB protocols. On data collection dates for adults, we arrived in city and town centers or at a host organization's location with a fully functional mobile laboratory (the size of a small RV) equipped with five private experimental workstations. We placed signage around the lab, indicating that adults who were regular smokers could participate in the study for $20 cash. If we had a host, that host would let their clientele know about our presence via Facebook, fliers, and word of mouth. Data collection most often occurred between 9am and 6pm. After obtaining informed consent, we confirmed participants as regular smokers through one of two biochemical validation procedures: (a) a CoVita

carbon monoxide detection breath test requiring at least 7 ppm (a result indicating regular smoking) or, in a handful of people with self-proclaimed breathing problems, (b) an Alere saliva test indicating a positive rating for the presence of cotinine (a nicotine metabolite). We only allowed qualifying participants to continue.

The adult sample identified as 64% male, 10% Hispanic, and 38% as non-White (n = 83 Black; n = 38 one or more non-White, non-Black categories). A majority (73%) had a total yearly household income of <$20,000/year, 67% reported their highest level of formal education being a high school diploma or less, 71% reported having utilized government food voucher services, and 59% reported being food insecure.

Youth

Youth participants (N = 340) were middle school students living in both rural and urban communities in the northeastern United States. We first identified communities via census data and contacts with partner organizations. We then reviewed publicly available data on the percentage of students who qualified for the federal free or reduced lunch program for low-income families. We completed district-level approval and permissions processes as required, and then approached qualifying schools (those with between 40% and 100% of students receiving free or reduced-price lunch) for permission to conduct the study with 6th to 8th grade students during school hours. Participating schools sent parents IRB-approved, opt-out consent forms in the weeks before we conducted the study, and each participant signed an assent form immediately before taking the study. Middle school students were not required to be smokers to participate.

Half (50%) of the youth respondents who provided information about gender identified as female, 44% as male, 3% "preferred not to answer," and another 3% did not respond. Participants had a median age of 12.6 (SD = 1.0; range 11–14). The majority (63%) identified as non-Hispanic White, 21% Black or African American, 12% Hispanic or Latino, 3% Native American, 2% Asian, and 13% another race or ethnicity. More than half (53%) reported living with a smoker, and 8% had tried at least a puff of a cigarette.

Study procedures

We assigned all participants a unique identifying number that contained details on their random assignment to one of five experimental conditions. We then escorted the participant into a private study station housed in the mobile laboratory and seated them for the study. Each station featured TobiiStudio eyetracking software and Tobii LCD monitors to unobtrusively collect data on the screen location of participants' eye gaze, as well as an iPad with the Qualtrics-based post-test questionnaire. Before viewing the stimuli for their randomized condition, each participant completed a nine-point, eye-tracking calibration process. Research assistants read the study instructions to participants, while those instructions were also visible on the screen. Participants completed all calibration tasks and viewed the images assigned to their condition while seated approximately two feet from the computer monitor.

Immediately after viewing the stimuli according to their assigned condition, we handed respondents an iPad to answer a series of closed-ended questions gauging emotional and cognitive reactions on a Qualtrics survey application. The average participant completed the study in 25 min, not including wait time. We paid each adult participant $20 cash upon study completion. For youth, we offered two incentive options to accommodate district policies and requests: $10 gift cards for students or a $10 per-student payment to the school to support student initiatives. The study took, on average, 15–20 min to complete, and students rarely had to wait to begin the study. We debriefed all participants about the rationale for the study.

Design and stimuli

As noted above, we randomly assigned participants to one of five conditions in which all participants viewed images of cigarette boxes depicting (1) FDA graphic full-color warnings (graphic FC), (2) FDA graphic black-and-white warnings (graphic B&W), (3) new FDA text-only warnings, (4) SGW text-only, or (5) brand-only control (see Figure 1). Each participant viewed a set of nine images of cigarette boxes, randomly ordered, consistent with their condition. The images appeared one at a time, automatically advancing after 10 s each, for 90 s of total screen time. An "X" appeared on the screen in one of nine possible locations in between images to reset the participant's gaze. The images depicted the front of cigarette boxes for the three most popular brands (Marlboro, Camel, and Newport) and for all conditions (except the brand-only control) featured a warning label placed prominently on the top 50% of the pack. Each brand appeared three times in the rotation of nine warnings; we rotated brands across warnings to prevent order effects and so that no one warning was consistently associated with any one brand. The graphic FC and graphic B&W conditions featured verbatim text and images from the FDA's nine warning labels proposed in 2011 with two exceptions. First, we modified the font on some labels to enable us to keep the font size and type consistent across conditions. Second, we omitted the 1-800-QUIT-NOW quit line number that was a part of the original FDA labels but was a source of controversy in litigation (R.J. Reynolds Tobacco Company et al. vs United States Food and Drug Administration, 2011). The new FDA text-only condition featured the same text from the graphic conditions but with the image removed and the text centered on a black background for aesthetic appeal. The SGW text-only condition rotated verbatim text (also on a black background) from the four warnings that are currently mandated on all cigarette boxes in the United States.

Dependent variables: eye tracking measures

Visual attention: gaze duration

We captured visual attention to specific areas of interest (AOIs) on the cigarette packs with eye-tracking technology. We used the Tobii T60XL 24" monitor (1920 × 1200 native resolution) with built in eye-trackers connected to computers with TobiiStudio 3.4.4 eye tracking software installed. We seated

Figure 1. Experimental stimuli in each of the five conditions. *Note*: We rotated the order and warning/brand combination of brands within conditions.

participants such that cigarette pack images were at a viewing distance of approximately 64 cm, decisions meant to replicate the angle and distance of holding a pack at arms-length. We instructed participants to keep their eyes on the screen for all images. We focused our analysis on the duration of fixation in three different AOIs (measured in seconds summed across all nine images): (a) brand logo (on the bottom 50% of the pack for noncontrol participants; the entire image for brand-only control participants), (b) warning (the top 50% of the pack for noncontrol), and (c) graphic pictorial images (for the conditions featuring images, graphic FC and graphic B&W).

Dependent variables: self-reported measures

After viewing the stimuli, participants completed a post-test questionnaire assessing self-reported affective and cognitive responses to the images. We randomized all measures within blocks and all blocks within the questionnaire except for emotional reactions, which we assessed first, and demographics, which we assessed last. We adapted all youth items from previous measures (described below) for potential low-literacy youth (targeting a 4th grade reading level).

Negative affect

We gauged emotional reactions immediately after viewing the stimuli using a set of eight items adapted from the Positive and Negative Affect Schedule (PANAS) (Watson & Clark, 1999). Participants responded to the prompt, "After looking at the pictures of cigarette packs, I felt…" [*afraid, angry, annoyed, sad, disturbed, grossed-out, scared,* and *guilty*] (randomly ordered). Response choices ran from $1 = $ *not at all* to $5 = $ *extremely*. Emotion items were highly correlated (average adult $r = .69$, average youth $r = .51$) and a single-factor, confirmatory factor model had acceptable fit (adults, CFI $= 0.99$, SMRR $= 0.03$; youth, Confirmatory Fit Index (CFI) $= 0.96$, Standardized root mean squared residual (SRMR) $= 0.04$), allowing us to treat negative affect as a unitary construct. We therefore averaged the items into a single scale (adults: $\alpha = .91$, $M = 2.12$, $SD = 1.00$; youth: $\alpha = .84$, $M = 2.23$, $SD = .91$).

Old risk beliefs, adults

We assessed health risk beliefs associated with both the old SGWs and the new FDA-proposed warnings using measures adapted from the Population Assessment of Tobacco and Health (PATH) survey (Hyland et al., 2016). We measured four items deemed "old risk beliefs" because their content

(explicit or implied) has been a part of SGW content for decades. We worded these items as follows: "Based on what you know or believe, does smoking cigarettes cause... [babies to be born with low birth weight from the mother smoking during pregnancy, heart disease in smokers, lung cancer in smokers, and lung disease, such as emphysema, in smokers]? We offered participants the response choices of Yes, No, and Not sure. We calculated an old risk belief index by first dichotomizing responses indicating Yes = 1 versus any other response = 0, and then totaling the number of "yes" responses across the four items (range 0–4, M = 3.61, SD = 0.91).

Old risk beliefs, youth

We measured four items among youth (adapted from PATH, Hyland et al., 2016), asking, "Do you believe cigarette smoking is related to... [cancer, lung disease, and heart disease, and problems in babies whose moms smoke]? Response choices ranged from 1 = definitely not to 4 = definitely yes. We calculated the old risk belief index by dichotomizing responses indicating definitely yes = 1 versus other responses = 0 and totaling the number of "definitely yes" responses across the four items (range = 0–4, M = 3.1, SD = 1.4).

New risk beliefs, adults

In addition, we assessed the health risk beliefs associated specifically with the new FDA-proposed labels that were not explicit or implied in any of the existing Surgeon General's Warning labels (also adapted from PATH, Hyland et al., 2016). Items for adults included: "Based on what you know or believe, does smoking cigarettes cause... [children to have breathing problems from secondhand smoke, lung disease in nonsmokers from secondhand smoke, stroke in smokers, and mouth cancer in smokers]. The response choices were Yes, No, and Not sure. We calculated a new health risk belief index by adding the number of responses for which respondents answered "yes" across the four items (range = 0–4, M = 3.32, SD = 1.04).

New risk beliefs, youth

We measured five items among youth (adapted from PATH, Hyland et al., 2016), for three of them asking, "do you believe cigarette smoking is related to... [health problems in non-smokers, stroke, and hole in the throat], as well as two related items posed as questions: Can smoking cigarettes kill you?, and Are cigarettes very addictive? Response choices ranged from 1 = definitely not to 4 = definitely yes. We again calculated a new health risk belief index by adding the number of responses for which respondents answered "definitely yes" across the five items (range = 0–5, M = 3.81, SD = 1.18).

Intentions to quit, adults

We measured quit intentions with three items adapted from the National Adult Tobacco Survey (Centers for Disease Control and Prevention, 2015):Do you want to quit smoking cigarettes for good? [Yes/No]; Do you have a time frame in mind for quitting? [Yes/No], and do you plan to quit smoking cigarettes for good... (In the next 7 days, In the next 30 days, In the next 6 months, In the next year, More than 1 year from now)? We created a dichotomous measure with planning to quit smoking in the next 6 months or earlier coded as "1"

(22%) and not planning to quit, not having a time frame in mind, or planning to quit smoking in >6 months coded as "0."

Susceptibility to smoke, youth

We gauged middle-school youth's susceptibility to smoking using following five items, adapted from validated instruments developed by Pierce, Choi, Gilpin, Farkas, and Merritt (1996) and Jackson (1998): Do you think that... you will smoke a cigarette soon?, you will smoke a cigarette in the next year?, you will be smoking cigarettes in high school?, in the future you might try a cigarette?, And if one of your best friends offered you a cigarette would you smoke it? Response choices ranged from 1 = definitely not to 4 = definitely yes. We considered youth who answered anything other than "definitely not" to any question as susceptible to smoking. This process deemed 42% of the sample as susceptible.

Control variables and analytic approach

Adults

We measured a variety of factors known to predict quit intentions, including levels of nicotine dependence using the Fagerstrom Test for Nicotine Dependence (Fagerström, 2012), and past quit attempts (in the past 12 months; Table 1). We assessed the impact of various warning label conditions on key dependent variables (DVs) using two methods: examining overlap of 95% confidence intervals between conditions (Table 2) and using multivariable models (ordinary least squares (OLS) or logistic regression, depending on the DV's level of measurement) to test for differences from the graphic FC condition while accounting for potential nonrandom assignment of demographics and risk factors (Table 3).

Table 1. Respondent demographics.

	Means (SD) or N's (valid %)	
	Study 1—Adults	Study 2—Youth
Age	M = 39.95 (13.27)	M = 12.57 (1.01)
Gender		
Male	198 (64.3%)	150 (45.3%)
Female	108 (35%)	171 (51.7%)
Prefer not to say	2 (0.6%)	10 (3%)
Hispanic	30 (9.8%)	41 (12.1%)
Race		
White	217 (69.3%)	216 (63.5%)
Black	83 (26.5%)	72 (21.2%)
Other	38 (12.1%)	59 (17.4%)
Smoking variables		
Nicotine dependence (range 0–10)	M = 5.39 (2.34)	–
Tried to quit in past 12 months	169 (54.5%)	–
Live with a smoker	–	181 (53.2%)
Tried a cigarette	–	28 (8.2%)
Respondent is colorblind	33 (10.7%)	24 (7.1%)
Income (Total yearly household)		
$0–$9,999	135 (44.4%)	–
$10,000–$19,999	88 (28.9%)	–
$20,000+	81 (26.6%)	–
Education		
High school graduate	190 (61.7%)	–
College graduate	26 (8.4%)	–
Benefits program recipient		
Emergency food	184 (59.7%)	–
WIC	52 (16.9%)	–
SNAP	220 (71.4%)	–

Note. N = 313 for adults. N = 340 for youth. Percentages are based on the number of respondents with non-missing data for that variable.

Table 2. Means and confidence intervals of dependent variables by condition.

Adults

	Fixation on Brand	Fixation on Warning	Fixation on Image	Negative Affect	New Risk Beliefs	Old Risk Beliefs	Intention to Quit	$n =$
Graphic FC	14.1	46.0	25.2	2.68	3.54	3.59	.21	61
	[11.7–16.5]	[41.7–50.4]	[22.3–28.2]	[2.41–2.94]	[3.31–3.77]	[3.36–3.82]	[.11–.31]	
Graphic B&W	16.1	38.0	19.1	2.49	3.47	3.78	.20	64
	[12.4–19.9]	[33.5–42.6]	[16.5–21.7]	[2.26–2.72]	[3.24–3.70]	[3.58–3.98]	[.10–.30]	
New FDA Text Only	17.9	40.5	–	2.01	3.26	3.60	.21	62
	[14.6–21.2]	[35.4–45.7]		[1.74–2.27]	[2.96–3.55]	[3.37–3.82]	[.11–.31]	
SGW Text Only	22.9	33.6	–	1.89	3.20	3.59	.25	64
	[18.7–27.2]	[29.0–38.1]		[1.68–2.10]	[2.96–3.45]	[3.39–3.80]	[.14–.36]	
Brand Only	53.9	–	–	1.54	3.15	3.47	.24	62
	[48.0–59.8]			[1.36–1.72]	[2.84–3.45]	[3.18–3.75]	[.14–.34]	

Youth

	Fixation on Brand	Fixation on Warning	Fixation on Image	Negative Affect	New Risk Beliefs	Old Risk Beliefs	Intention to Quit	$n =$
Graphic FC	16.9	42.6	25.0	2.25	3.93	3.00	.43	69
	[14.9–18.9]	[39.4–45.7]	[22.8–27.1]	[2.04–2.47]	[3.64–4.21]	[2.65–3.35]	[.31–.55]	
Graphic B&W	15.6	38.9	21.0	2.37	3.91	3.24	.41	68
	[13.4–17.7]	[34.7–43.1]	[18.3–23.7]	[2.14–2.60]	[3.61–4.21]	[2.91–3.57]	[.29–.53]	
New FDA Text Only	18.2	36.6	–	2.36	4.05	3.25	.38	65
	[15.5–20.9]	[32.9–40.4]		[2.12–2.61]	[3.79–4.30]	[2.95–3.57]	[.26–.50]	
SGW Text Only	17.4	38.1	–	2.37	3.67	3.25	.42	67
	[15.4–19.5]	[34.7–41.5]		[2.14–2.60]	[3.39–3.95]	[2.94–3.57]	[.30–.54]	
Brand Only	53.3	–	–	1.82	3.56	2.96	.44	71
	[49.0–57.5]			[1.66–1.98]	[3.26–3.86]	[2.60–3.31]	[.32–.56]	

Note: Cells report the total fixation duration in seconds across all nine packs. FC = Full color; B&W = Black and white; FDA = Food and Drug Administration; SGW = Surgeon General's warning.

Youth

In addition, we measured several known predictors of smoking susceptibility, including previous smoking behavior (*Have you ever tried smoking a cigarette, even one or two puffs?* 8% answered "*yes*"), sensation seeking (using three items of a scale adapted for youth by Jensen, Weaver, Ivic, & Imboden, 2011; α = .78, *M* = 2.04, *SD* = .78), and whether anyone living in their home smoked cigarettes (53%; measure adapted from Centers for Disease Control and Prevention, 2014; see Table 1). As with adults, we assessed the impact of various warning label conditions on key DVs by examining overlap of 95% CIs between conditions (Table 2) and using multivariable models (OLS or logistic regression, depending on the DV's level of measurement) to test for differences from the graphic FC condition while accounting for potential nonrandom assignment of demographics and risk factors (Table 4).

Results

Visual attention

Adults

Results from the first three columns in Tables 2 and 4 indicate that participants dwelled on the brand/logo area of the packs (bottom 50%) for more time in the SGW text condition than for any other condition with FDA text (FDA text only, graphic FC, and graphic B&W). Respondents viewing graphic FC warnings spent more time looking at the warning (top 50%) than those viewing graphic B&W or SGW text-only. In addition, participants looked at the image AOI (text excluded) longer if it was in color than if it was in black and white.

Youth

The results from the first three columns in Tables 2 and 4 indicate that there were no differences by warning condition (excluding the

brand-only control group) on visual attention to the brand/logo area of the packs (bottom 50%). Youth viewing graphic FC warnings spent more time looking at the warning (top 50%) than those viewing new FDA text-only. Youth also looked longer at the graphic part of the image (not the text) if it was in FC than if it was in B&W.

Negative affect

Adults

Respondents exposed to graphic warning labels (in FC or B&W) reported greater negative affect than those exposed to either text-only condition or the brand-only control (Tables 2 and 3). Respondents exposed to text-only labels (new FDA or SGW) also reported more negative affect than respondents exposed to the brand-only condition (Table 2).

Youth

Respondents exposed to any warning label (graphic or text-only) reported greater negative affect than those exposed to the brand-only control (Tables 2 and 5).

Health risk beliefs, intentions to quit and smoking susceptibility

There were no significant differences ($p < .05$) between any of the randomized conditions in levels of risk beliefs (old or new) quit intentions, or smoking susceptibility (Tables 2, 3 and 5).

Discussion

Summary of findings

This study compared how exposure to less extensive alternatives to the full-color graphic warnings proposed by the FDA

Table 3. Regression models predicting visual fixation, negative affect, risk beliefs, and intention to quit (adults).

	Fixation on Brand	Fixation on Warning	Fixation on Image	Negative Affect	Old Risk Beliefs	New Risk Beliefs	Intention to Quit
Condition (vs. GFC)							
Graphic B&W	1.15 (3.15)	−7.37 (3.60)*	−6.78 (2.26)**	−.17 (.17)	.29 (.17)	−.01 (.20)	−.17 (.51)
New FDA text only	2.81 (3.04)	−5.11 (3.48)	–	−.62 (.17)***	.02 (.17)	−.24 (.19)	−.01 (.48)
SGW text only	9.17 (3.07)**	−11.19 (3.50)**	–	−.81 (.17)***	.05 (.17)	−.29 (.19)	.38 (.47)
Brand only	39.39 (3.07)^	–	–	−1.14 (.17)***	−.08 (.17)	−.33 (.19)	.17 (.47)
Covariates							
Age	−.17 (.08)*	−.06 (.10)	−.08 (.09)	.01 (.00)	.00 (.00)	−.00 (.01)	.01 (.01)
Male (vs. female)	1.81 (2.12)	1.01 (2.74)	1.88 (2.49)	−.32 (.12)**	.07 (.12)	−.10 (.13)	.09 (.34)
Other gender (vs. female)	−3.03 (16.87)	−8.62 (19.30)	9.85 (12.22)	−1.66 (.93)	−3.59 (.93)***a	−1.90 (1.07)	−19.3 (4e^5)
Hispanic	.27 (3.42)	.43 (4.41)	−6.86 (4.62)	.46 (.19)*	−.34 (.19)	−.24 (.22)	−.07 (.51)
Black	−.71 (2.28)	3.06 (3.03)	−2.00 (2.68)	.37 (.13)**	−.19 (.13)	−.27 (.14)	.44 (.34)
Other, non-White race	1.61 (3.14)	9.45 (4.34)*	4.90 (3.64)	−.34 (.17)*	.15 (.17)	−.01 (.20)	.17 (.46)
$10K-$19K (vs. <$10K)	3.43 (2.40)	3.85 (3.16)	2.45 (2.78)	.06 (.13)	.04 (.13)	−.08 (.15)	.54 (.36)
$20K+ (vs. < $10K)	−.27 (2.80)	−2.81 (3.67)	1.43 (3.50)	−.02 (.15)	−.01 (.15)	.01 (.18)	−.14 (.44)
High school (vs. no HS)	.91 (2.13)	−1.16 (2.74)	.40 (2.38)	.04 (.12)	.03 (.12)	.00 (.14)	.37 (.34)
College (vs. no college)	1.78 (3.70)	−2.81 (4.77)	.39 (4.77)	.00 (.19)	−.01 (.20)	.24 (.23)	.49 (.48)
Nicotine dependence	−.13 (.44)	.16 (.56)	.08 (.49)	.00 (.02)	−.03 (.02)	−.03 (.03)	−.01 (.07)
Previous quit attempt	−1.41 (2.01)	.33 (2.58)	1.99 (2.36)	.19 (.11)	.02 (.11)	.12 (.13)	1.05 (.33)**
Emergency food	−.76 (2.54)	−4.89 (3.36)	2.81 (3.24)	−.05 (.14)	.09 (.14)	.16 (.16)	−.31 (.39)
WIC recipient	−2.67 (2.76)	4.28 (3.47)	.17 (2.91)	.12 (.15)	.10 (.15)	.19 (.17)	.53 (.40)
SNAP recipient	−2.06 (2.66)	−3.13 (3.35)	.87 (2.88)	.13 (.15)	.05 (.15)	.39 (.17)*	.12 (.42)
Colorblind	2.84 (3.16)	−3.59 (4.15)	1.45 (3.87)	.19 (.18)	.11 (.17)	.19 (.20)	−.26 (.52)
Constant	19.13 (5.90)***	50.24 (7.53)***	25.96 (6.80)***	2.67 (.32)***	3.56 (.32)***	3.75 (.37)***	−.91 (.91)
Adjusted R^2	.44	.04	−.01	.20	.04	.05	-
N	294	231	113	299	299	299	299

Note. Cells present unstandardized regression coefficients and standard errors. All models were ordinary least squares (OLS) regressions except for the model predicting susceptibility to smoke, which was a logistic regression model. ^ denotes that the control condition had no nonbrand area of interest (AOI) and was thus highly significant (p < .001). *p ≤ .05, **p ≤ .01, ***p ≤ .001. a This coefficient should be interpreted with caution, because very few respondents (n = 2) identified as other gender. GFC = Graphic full color; B&W = Black and white; FDA = Food and Drug Administration; SGW = Surgeon General's warning.

influences key variables proposed in the message impact framework. We observed some consistent patterns as well as differences across the two studies.

First, we find that graphic FC images hold visual attention. Both adult smokers and youth assigned to view FC graphic warnings spent more time looking at the graphic image (i.e., diseased lungs) than those who saw the same image in B&W. Adult smokers also looked at the overall warning for a longer period of time when assigned to graphic FC warnings compared to graphic B&W or SGW text-only versions, while youth looked at the graphic FC warnings longer than the FDA text-only warning. Differences in visual attention between graphic FC and other conditions, for both populations, were nonsignificant but similar in magnitude and always longest in the graphic FC conditions. We thus conclude that the overall pattern for both populations is consistent with the conclusion that graphic FC warnings garner the most attention, possibly owing to a combination of attracting viewers to the images and processing the new text.

Second, we find that warnings elicit negative affect. Among adult smokers, exposure to GWLs (in this case, both graphic FC and graphic B&W) produced greater negative affect than both text-only warning conditions and control. Whether these GWLs were in FC or B&W did not matter. Among middle-school youth, the pattern was quite different: exposure to any set of warning labels increased negative affect in participants compared to the control packs without warnings. Given that TCs argued that the U. S. government labels imposed emotionally charged message without any new health information, one key finding is that while warnings with images are highly associated with negative emotion for adults, the new labels do not necessarily generate any more emotion for youth than simply putting the SGWs warning on the front of the box.

Third, across both youth and adult smokers, those who viewed graphic FC warning labels did not report a significant increase in old or new risk beliefs, intentions to quit (among adult smokers), or susceptibility to smoke (among youth) compared to those assigned to other label conditions. All indices of risk beliefs were very high (suggesting the potential for ceiling effects), and we did not design our randomized experiments to have sufficient statistical power to detect effects on quit intentions or smoking susceptibility of the magnitude typically found in clinical trials or observational studies (e.g., Brewer et al., 2016; Noar et al., 2016b). The message impact framework (Noar et al., 2016a, 2016b) also suggests that these downstream effects are likely mediated by affective responses to warning labels. Thus, it is unreasonable to expect to observe direct effects on quit intentions or smoking susceptibility in response to a single session featuring 90 s of exposure. We did run a series of subsequent analyses in which we predicted (a) quit intentions as a function of all variables included in Table 3 (excluding the warning label conditions but adding negative affect to the model) and (b) smoking susceptibility as a function of all variables included in Table 4 (again excluding the warning label conditions but adding negative affect to the model). These analyses showed that the negative affect was a robust predictor of quit intentions among adult smokers (B = 0.30, odds ratio = 1.36, p = 0.04) and both new risk beliefs (standardized beta = 0.24, p < 0.001) and old risk beliefs (standardized beta = 0.23, p < 0.001) among youth. These results echo strong and consistent evidence from previous studies (e.g., Byrne et al., 2015; Brewer et al., 2016; Evans et al., 2015; Noar et al., 2016b) supporting the assertion that negative affect is likely to translate into favorable, downstream effects on quit intentions among smokers and health risk perceptions among (largely nonsmoking) youth.

Table 4. Regression models predicting visual fixation, negative affect, risk beliefs, and susceptibility to smoke (youth).

	Fixation on Brand	Fixation on Warning	Fixation on Image	Negative Affect	Old Risk Beliefs	New Risk Beliefs	Susceptible to Smoke
Condition (vs. GFC)							
Graphic B&W	−2.17 (2.04)	−4.23 (2.67)	−4.01 (1.93)*	.10 (.16)	.35 (.24)	.14 (.21)	−.09 (.40)
New FDA text only	1.25 (2.08)	−6.04 (2.73)*	–	.02 (.16)	.28 (.25)	.16 (.21)	.14 (.41)
SGW text only	.50 (2.02)	−5.07 (2.65)	–	.04 (.16)	.28 (.24)	−.23 (.20)	.13 (.41)
Brand only	36.02 (2.01)^	–	–	−.47 (.16)**	.06 (.24)	−.28 (.20)	.12 (.39)
Covariates							
Age	−.13 (.672)	.35 (.99)	−.11 (1.00)	−.06 (.05)	.12 (.08)	.16 (.07)*	−.16 (.13)
Male (vs. female)	−.85 (1.324)	−3.88 (1.95)*	1.32 (1.93)	−.09 (.10)	.23 (.16)	.13 (.13)	−.11 (.26)
Other gender (vs. female)	−2.90 (3.67)	5.16 (5.34)	2.79 (4.88)	−.14 (.29)	.39 (.45)	.51 (.38)	−2.28 (1.10)*a
Hispanic	−3.57 (2.75)	6.63 (4.09)	−3.30 (4.47)	−.42 (.22)*	.27 (.33)	.14 (.28)	.36 (.54)
Black	−3.28 (1.89)	−.71 (2.84)	−.05 (2.94)	−.05 (.14)	.07 (.22)	.15 (.18)	.42 (.35)
Other, non-White race	−2.12 (1.74)	−2.27 (2.56)	.08 (2.59)	.05 (.13)	.10 (.21)	.16 (.17)	.23 (.34)
Previous smoking	−3.19 (2.39)	−.48 (3.30)	.38 (3.21)	−.09 (.19)	.50 (.29)	.35 (.25)	2.02 (.60)***
Smoking environment	−.16 (1.32)	.29 (1.94)	−1.89 (2.02)	.06 (.10)	−.23 (.16)	−.26 (.13)*	.85 (.26)***
Sensation seeking	.56 (.86)	.50 (1.27)	−.33 (1.28)	−.12 (.07)	−.05 (.10)	.00 (.09)	.89 (.18)***
Colorblind	1.24 (2.52)	4.87 (3.58)	1.95 (3.35)	−.12 (.19)	.35 (.30)	.35 (.25)	−.20 (.50)
Constant	19.48 (8.39)*	38.39 (12.37)***	27.09 (12.66)*	3.33 (.64)***	1.43 (.97)	1.85 (.81)*	−.85 (1.59)
Adjusted R^2	.64	.01	−.02	.05	.01	.04	–
N	303	240	123	324	329	328	329

Note. Cells present unstandardized regression coefficients and standard errors. All models were ordinary least squares (OLS) regressions except for the model predicting susceptibility to smoke, which was a logistic regression model. ^ denotes that the control condition had no nonbrand area of interest (AOI) and was thus highly significant ($p < .001$), *$p \leq .05$, **$p \leq .01$, ***$p \leq .001$. [a] This coefficient should be interpreted with caution, because very few respondents ($n = 10$) identified as other gender. GFC = Graphic full color; B&W = Black and white; FDA = Food and Drug Administration; SGW = Surgeon General's warning.

Study implications

[faded/illegible paragraph]

these studies among two populations that one would expect to be very difficult to influence—adult smokers from highly disadvantaged socioeconomic backgrounds (who experience immense barriers to quitting) and middle-school youth at high risk of future smoking uptake (owing to high rates of living with smokers and similarly economically disadvantaged backgrounds). We thus conclude that the current study does not rule out the possibility that graphic FC warnings offer incremental benefits over less extensive alternatives, as is evidenced by a large international research base demonstrating that pictorial warnings result in intended effects over time. It is therefore plausible that the incremental benefits observed here may scale up toward a larger impact at the population level.

Limitations and future research

As noted above, it is important to consider that the exposure in this study takes place over 90 s. If FC warning labels are implemented in the United States, the levels and durations of exposure will be considerably longer and more frequent. We cannot speak the

effects of repeated exposure to attention-grabbing, graphic FC warning labels. These studies reported here also rely on self-reported measures to gauge both emotional reactions and health risk beliefs, suggesting that future studies examine the effects of these label manipulations on behavioral outcomes measured over a longer period of time. In addition, we used brand imagery from three specific TCs in an effort to assess visual attention to warning labels versus branded content. However, our study did not include a variety of other brands that smokers may use regularly.

We did not examine the aspects of all of the legal challenges to the Tobacco Control Act. Particularly, the FDA has the authority to place GWLs on ads for cigarettes. Cigarette ads often market their product by depicting attractive, social youth engaged in cool activities. On the one hand, these visual depictions of benefits of smoking might distract from the warnings, but one could easily argue the opposite might be true. If warnings on ads distract from elements compelling youth to take up smoking, the warnings could provide a public health benefit.

Conclusion

This study offers new evidence on the relative importance of graphic full color, graphic black and white, and text-only cigarette warning labels in shaping visual attention, negative affect, and health risk beliefs. The results reveal that graphic full-color images held visual attention for a longer duration than less restrictive alternatives. Graphic images (whether in full color or in black and white) also produced higher levels of negative affect among adult smokers, but graphic images did not outperform text-only warnings of similar magnitude among at-risk but largely nonsmoking, middle-school youth. Findings raise important new questions about the optimal design of GWLs to increase cessation among adult smokers and increase understanding of the health risks of smoking among youth from socioecomically disadvantaged backgrounds.

Disclosure of potential conflicts of interest

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Do the Ends Justify the Means? A Test of Alternatives to the FDA Proposed Cigarette Warning Labels

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Three studies provide empirical, social scientific tests of alternatives to the originally proposed U.S. Food and Drug Administration (FDA) cigarette package warning labels on health risk beliefs, perceived fear, and effectiveness. Our research addresses questions at the root of the legal disputes surrounding FDA regulation of cigarette package warning labels. Specifically, we describe results from three studies that investigate the mediating role of health beliefs and perceived fear in shaping message effectiveness and intentions to quit. The first study featured nonsmoking young adults, while the second and third studies sampled adult daily smokers. Each study was a randomized experiment with five warning-label image conditions: full–color graphic warning labels, black-and-white graphic warning labels, warning text (no graphic image), Surgeon General's warning labels, and no warning. Results consistently indicate that graphic warning labels (in both color and black-and-white) promote increased perceptions of fear, which in turn are associated with greater (perceived and actual) effectiveness. We conclude with a discussion of the results, highlighting implications, public policy considerations, and suggestions for future research.

Tobacco usage, primarily cigarette smoking, is responsible for almost half a million preventable deaths in the United States each year and contributes significantly to the high rates of other long-term health concerns including several cancers, emphysema, and heart disease (Food and Drug Administration [FDA], 2012). The need to curtail and prevent tobacco usage has been acknowledged as a major U.S. public health concern, and a number of different policy regulations are in place to address this issue (Family Smoking Prevention and Tobacco Control Act, 2009). For

example, smoking is no longer permitted in workplaces, including bars and restaurants, in 36 states (Americans for Nonsmokers' Rights, 2012); cigarette packages are taxed at a higher rate than other products (Centers for Disease Control and Prevention, 2012); and sale of tobacco is restricted to adults over age 18 years (Campaign for Tobacco-Free Kids, 2012). One of these regulations requires that health warning labels appear on cigarette packages (Cigarette Labeling and Advertising Act, 1965).

In 2009, the Family Smoking Prevention and Tobacco Control Act, 2009 (Family Smoking Act) granted authority to the U.S. Food and Drug Administration (FDA) to implement graphic warning labels on cigarette packages in the United States. Not surprisingly, tobacco companies opposed these graphic warning labels, claiming that the messages "unjustifiably and unduly burden [their] commercial speech

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... [and] unconstitutionally compel [them] to disseminate the Government's anti-tobacco message" (*R.J. Reynolds Tobacco Company, et al., v. United States Food and Drug Administration, et al.*, 2011, p. 11). The case worked its way through the courts and a court of appeals held that the particular graphic warning labels proposed by the FDA violated the First Amendment, while still upholding the provision of the act that provided the FDA authority to develop and adopt graphic warning labels (Holder, 2013). The U.S. government decided not to pursue an appeal to the Supreme Court of the United States at this time, opting instead to rework the content of the warning labels.

Reaction to the FDA's decision not to pursue the appeal to the Supreme Court has emphasized the need for social scientific research on the effectiveness of alternatives to the originally proposed graphic warning labels (Holder, 2013). There is a long history of using social science research to support legal and policy decisions, and this trend is continuing to grow as the courts are willing to consider social scientific findings in their rulings (Caplan, Morrison, & Stambaugh, 1975; Cook, King, & Laitin, 2010; King, 2011; Monahan & Walker, 2010; Morgan & Pullin, 2010).[1]

Drawing upon communication theory and the claims made in the recent legal dispute, this article offers social scientific tests of alternatives to the originally proposed FDA full-color graphic warning labels. We aim to provide information relevant to the FDA's efforts to rework the labels.

CIGARETTE WARNING-LABEL EFFECTIVENESS

Cigarette warning labels have been included on packages sold in the United States since the Cigarette Labeling and Advertising Act of 1965. However, sales continued to increase following the initial adoption of warning labels (Givel, 2007). These original text-based warnings have been revised twice, once to include reference to the Surgeon General and, most recently, in the mid 1980s to include four rotating text-based warnings mentioning specific health consequences, such as "Surgeon General's Warning: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy" (Comprehensive Smoking

Education Act, 1984). However, researchers and public health officials have expressed concern that the current text-based U.S. warning labels are largely symbolic and not effective in actually lowering smoking rates (Givel, 2007).

Currently, 168 countries around the world have signed the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) treaty, which sets forth a comprehensive tobacco control policy that includes standards for pictorial warning labels (World Health Organization, 2013). The United States has signed, but not yet ratified, the WHO FCTC. Research has argued that warning labels with graphic representations are more effective than text-only labels without graphics (Givel, 2007; Hammond, 2011; Hammond, Fong, McNeill, Borland, & Cummings, 2006; Thrasher et al., 2012). Research has indicated that in comparison to text-based warnings, pictorial warning labels make smokers likely to think about the health risks of smoking (Bansal-Travers, Hammond, Smith, & Cummings, 2011), endorse health risks (Hammond, 2011; Hammond et al., 2006), perceive the warnings as more effective (O'Hegarty et al., 2006), notice the warnings (White, Webster, & Wakefield, 2008), have increased perceptions of harm (McCool, Webb, Cameron, & Hoek, 2012), and indicate greater severity of risk due to smoking (Schneider, Gadinger, & Fischer, 2012). While this body of research is promising, it is important to note that many of these studies have featured a correlational design, and some of the effectiveness measures may be related to other tobacco cessation initiatives, such as increased taxes, that took place concurrently (Azagba & Sharaf, 2013; Hammond, 2011; Peters et al., 2007). Overall, research indicates that in many countries outside the United States graphic warning labels are a promising strategy for discouraging tobacco use.

THE CASE HISTORY AND LEGAL PRECEDENT

In June 2009, U.S. President Barack Obama signed the Family Smoking Prevention and Tobacco Control Act, 2009 (H.R. 1256). This law provides the Food and Drug Administration (FDA) with the authority to regulate tobacco products, including implementing graphic health warning labels on cigarette packages. Specifically, the ruling states that the "secretary shall issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the [new warning] label statements" [H.R. 1256, Division A, Title 2, Sec. 201(d)]. The ruling explains that the warning labels would appear on the top 50% of both sides of cigarette packages, with text in at least 17-point font and color graphic representations of health consequences.[2]

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[1] In *Daubert v. Merrell Dow Pharmaceuticals, Inc* (1993), the Supreme Court first set out a series of standards for the use of research in legal cases. For example, the Court must not simply rely upon the evidence of experts, but it has a more direct obligation to evaluate the evidence and determine its suitability (Monahan & Walker, 2010). That said, the use of social scientific evidence within the legal system and policy domains is not without challenges. Mertz (2011) notes that legal practitioners do not always value the lack of certainty associated with scientific results or are, at times, assuming the findings suggest more certainty than they do. In other words, the courts seek deterministic causal evidence, while much scientific evidence provides results supporting probabilistic causal claims (Langleben & Moriarty, 2012). From the perspective of health policy, it is important to recognize the diversity of disciplinary perspectives and to consider the types of questions social science research can best answer (Gilson et al., 2011).

[2] Following approval of the Family Smoking Act, several cigarette companies filed suit, in *Commonwealth Brands Inc., et al v. United States of America, et al.*, in Kentucky Western District Court, claiming that the warning label requirements in the Family Smoking Act violate their First

In June 2011, the FDA publicly released nine approved graphic warning labels, each featuring a full-color graphic image and corresponding text statement associated with cigarette usage. The labels were selected after comparison tests indicated they would be more effective than other designs (Nonnemaker et al., 2010). Eight of the labels focus on health consequences associated with smoking, including death, disease, and complications with pregnancy and delivery. One label depicts rewards associated with quitting smoking and features a healthy-looking man proud to have quit. Major tobacco companies immediately filed suit in *R.J. Reynolds Tobacco Company, et al., v. United States Food and Drug Administration, et al.* Tobacco companies objected to the format of the proposed FDA warnings labels, especially the full-color, graphic images prominently displayed on both sides of the box, as a violation of their rights to commercial speech in marketing a legal product. Tobacco company documents indicate cigarette packages are an essential component of their marketing strategy (Wakefield, Morley, Horan, & Cummings, 2002). The specific factors at issue were that the proposed warning labels include a graphic image, appear in color, and are featured in a prominent position on the top half of the box.

The tobacco companies highlighted a number of key legal cases in support of their claim (*Ibanez v. Florida Department of Business and Professional Regulation*, 1994; *Entertainment Software Association v. Blagojevich*, 2006). At issue in all of these cases is the doctrine on commercial speech established in the landmark ruling *Central Hudson Gas & Electric Corp . v . Public Service Commission* (1980). The *Central Hudson* case established a four-factor test for the constitutional protection of commercial speech, noting the product or service must be lawful and truthful (factor 1), and a regulation that restricts commercial speech must relate to (factor 2) and advance a substantial government interest (factor 3), and not be more extensive than necessary (factor 4) (Hoefges & Sanchez, 2000; Shectman, 2011).[3] In other words, the regulation should be the least extensive necessary to achieve the government interest. In recent years, the courts have afforded the same commercial speech protection for so-called "vice products," such as tobacco and liquor, as they have for other products (Hoefges & Sanchez, 2000). Ultimately, a federal appeals court ruled on *R.J. Reynolds Tobacco Company, et al., v. United States Food and Drug Administration* in favor of the tobacco companies.[4] Instead

of appealing the decision to the Supreme Court, the U.S. government decided to revisit the labels.

LEGAL RATIONALE

As noted earlier, most of the decisions using *Central Hudson* have been based on (1) whether or not the policy is more extensive than necessary and (2) whether it advances a substantial government interest. Therefore, while the FDA is revisiting the graphic warning labels, it must consider alternatives that both meet the compelling government interest and are not more extensive than necessary to achieve the intended effect. We now review these two concepts and how they relate to the issue at hand.

Least Extensive Means

One factor at issue is whether full-color graphic warning labels are more extensive than is necessary to achieve the compelling government interest. From a legal perspective, it is important to test alternatives based on less extensive regulations in order to determine whether the various parameters are necessary to fulfill the compelling government interest. The government has the obligation to use the least extensive means to further its public health interest. In their legal arguments, the tobacco companies take issue with a number of specific message elements, such as the use of color, the use of the graphic image, and the placement of the warning label. In other words, under the *Central Hudson* framework, it would not be enough for the selected warning labels to be effective. The government may also need to show, in future litigation, that this effect cannot be achieved through a less extensive regulation. As the FDA is currently reworking the warning labels, it is important to test elements that were disputed in the original lawsuit as these issues are likely to reemerge after the new labels are presented.

Compelling Government Interest

The second factor at issue is that the warning labels must fulfill a compelling government interest. The FDA claimed the full-color graphic warning labels "more effectively convey the extraordinary, undisputed health risks created by the use of [cigarettes]" (*R.J. Reynolds Tobacco Company, et al., v. United States Food and Drug Administration, et al.*, 2011, document 18, p. 3). It claimed that the warnings more "effectively convey the negative health consequences of smoking" than the current Surgeon General's warning labels (*R.J. Reynolds Tobacco Company, et al., v. United States Food and Drug Administration, et al.*, 2011, document 18, p. 23).

Amendment rights and are therefore unconstitutional. While the District Court declared two provisions of the act unconstitutional, it upheld most of the provisions, including the new warning label requirements.

[3]Several Supreme Court justices have questioned the usefulness of the *Central Hudson* test. For example, in the *44 Liquormart Inc. v. Rhode Island* (1996) case, Justice Thomas advocated that the government should not restrict truthful commercial speech about lawful products and services (Waters, 1997).

[4]Circuit Judge Judith W. Rogers dissented with the court's decision and argued that *Zauderer v. Office of Disciplinary Counsel,* 1985 provided a better standard than *Central Hudson* (Holder, March 15, 2013). The Zauderer

standard would require the government to show only that the labels are "reasonably related to its stated and substantial interest in effectively conveying this information to consumers" (Holder, March 15, 2013).

However, the government and the tobacco companies have differing conceptualizations of this government interest. The larger goal of the FDA is to "have a significant public health impact by decreasing the number of smokers, resulting in lives saved, increased life expectancy, and lower medical costs" (FDA, 2013). The FDA argues that the full-color graphic warning labels are necessary in order to achieve this government interest. Their claim is that "the new warnings serve as a *reminder* of the negative health consequences of smoking every time somebody picks up a pack of cigarettes or views a cigarette advertisement" (FDA, 2013, emphasis added). Therefore, the FDA recognizes that smokers may understand the health risks of smoking cigarettes, but reminders may be necessary to curtail use.

Tobacco companies have interpreted the compelling government interest primarily as increasing knowledge of health risk beliefs in their legal arguments in opposition to the FDA graphic warning labels. They argue that the public is already aware of the health risks of smoking cigarettes. Major tobacco companies maintain that the FDA full-color graphic warning labels will not have a "material impact on consumers' understanding of smoking risks." (*R.J. Reynolds Tobacco Company, et al., v. United States Food and Drug Administration, et al.*, 2011, document 18, p. 23). Furthermore, they claim that people overestimate the risks associated with smoking cigarettes, and therefore the proposed packages may not be contributing to increasing accurate beliefs regarding the health consequences of smoking (Schneider et al., 2012). Therefore, a key debate in the legal discussion is whether the FDA warning labels must communicate a more accurate understanding or, alternatively, provide a reminder of health risks already known.

One claim made by the tobacco companies is that the graphic warning labels amount to the government requiring an "emotionally charged anti-smoking message" (*R.J. Reynolds Tobacco Company, et al., v. United States Food and Drug Administration, et al.*, 2011, document 18, p. 14). In other words, they claim that the warning labels create a negative emotional response, rather than accurate health risk beliefs. The Canadian pictorial warning labels have been found to produce a more negative emotional reaction to smoking-related cues (Peters et al., 2007). These arguments raise the question of whether or not cigarette warning labels need to generate fear in order to be effective.

THEORY ON THE ROLE OF FEAR IN HEALTH MESSAGING

Strategic messages that generate fear aim to get the attention of those at risk and to motivate the individual to make a behavioral change in an effort to reduce the fear (Yzer, Southwell, & Stephenson, 2013). Communication theory further suggests that risk beliefs and fear are intertwined.

For example, the Extended Parallel Process Model (EPPM) conceptualizes fear as a product of two risk-related beliefs: threat susceptibility and threat severity (Witte, 1992, 1994). Messages may generate fear by emphasizing the severity of an outcome or by highlighting a harm expected from a threat (Rogers, 1975). When both threat susceptibility and severity are high, audiences are likely to experience fear, and communication scholars have long acknowledged the potential mediating role of fear in the effectiveness of persuasive messages (Rogers, 1975; Witte, 1992; Witte & Allen, 2000). Because fear is a discrete negative emotion, it is theoretically followed by the desire to find a way to alleviate that feeling (Dillard & Nabi, 2006), and in the case of health messages, the desired method of alleviation is behavior change. In other words, messages that illustrate threat susceptibility and severity can generate fear, which motivates the audience toward behavior change in an effort to reduce that fear. Prior research has indeed found that highly graphic images evoke fear, which in turn promotes intentions to quit smoking (Kees, Burton, Andrews, & Kozup, 2011). In Kees et al. (2011), the researchers manipulated a pictorial warning featuring mouth disease into several conditions: mild image, moderate image, highly graphic image, and no image. The highly graphic image, in particular, was designed to be fear-evoking, and it produced greater intention to quit, but less ability to recall the text portion of the message. The authors then concluded that increased motivation to quit arose due to fear, not via recalling the message's content.

If tobacco companies are correct in their claim that the public already knows the health risks of smoking cigarettes, one way to generate a behavioral change may be through motivation to alleviate feelings of fear resulting from being reminded of the susceptibility and severity of smoking's negative health consequences. In other words, the pictorial depictions of graphic warning labels could highlight or remind the public about the consequences of smoking cigarettes that they already know, generating feelings of fear, which may in turn be a necessary factor in message effectiveness.

In light of the legal and theoretical rationales highlighted in the preceding, we offer four research questions (RQs) to guide the design, analysis, and interpretation of study results:

RQ1: Are label alternatives, based on less extensive regulations, less effective than the full-color graphic warning labels?

RQ2: Is there a label alternative, based on a less extensive regulation, that is similarly effective to the full-color graphic warning label?

RQ3: Do alternatives, based on less extensive regulations, generate lower levels of fear and health risk beliefs?

RQ4: Do health risk beliefs and/or fear mediate the relationship between exposure to the warning label alternatives (at varying levels of regulatory action) and effectiveness?

STUDY 1 METHOD

Participants

One hundred and seventy-one students at a large, Northeastern university completed study 1 in exchange for extra credit. Thirty-six participants who reported smoking cigarettes, including one daily smoker and 35 who reported smoking occasionally or when they drink, were removed from analysis since smokers are the focus of studies 2 and 3. Therefore, the sample in Study 1 consists of 135 nonsmoking young adults. They were recruited during the 2011–2012 academic year through an online, university-operated research pool, and provided consent through an institutional review board (IRB)-approved form. Participants ranged in age from 18 to 33 years ($M = 20.15$; $SD = 1.95$); 44 were male and 91 were female.

Procedure

All participants completed an online pretest, responding to questions about their current smoking behavior. Twenty-four hours later, we sent participants a link to the main study. We randomly assigned participants to view one of five conditions. We first gave all participants a set of on-screen instructions before viewing on-screen images of 9 different cigarette package fronts, one at a time, for 10 seconds each. There were between 26 and 29 participants in each randomly assigned condition.

We manipulated photos of cigarette package fronts according to each participant's assigned condition (described in the following). We placed the labels on the top half of market-leading cigarette brand package fronts (including Marlboro, Marlboro Light, Newport, and Camel; the pairings themselves were not rotated). Therefore, each participant saw each brand more than once in the nine-label rotation.

Following the presentation of stimuli, participants completed the dependent measures described below. Participants were then fully debriefed.

Warning Label Manipulation

The term *warning text* refers to the nine text statements put forth in the Family Smoking Act and utilized in the originally proposed FDA warning labels. The term *graphic images* refers to the photos and illustrations that accompanied the originally proposed FDA warning text, and the term *graphic warning labels* refers to the entire proposed warnings (text and image, when combined). To test our hypotheses, we developed five conditions (see Figure 1).

Condition 1—Full-color graphic warning labels. Participants in Condition 1 viewed all nine of the originally proposed FDA graphic warning labels. These labels feature graphic images, cover 50% of the cigarette package size, and appear in full color. For the most part, the graphic images portray negative consequences of smoking, such as diseased lungs, rotten teeth and lip cancer, and tracheostomy hole. Most of the warning text statements paired with these images point out health risks associated with smoking cigarettes, such as *cigarettes cause fatal lung disease*, *cigarettes cause cancer*, and *cigarettes are addictive*.

Condition 2—Black-and-white graphic warning labels. Participants in Condition 2 also viewed all nine originally proposed FDA graphic warning labels, but the FDA images appeared in black and white instead of full color.

Condition 3—Warning text (no graphic image). Participants in Condition 3 viewed all 9 of the originally proposed FDA warning text statements. In other words, the accompanying graphic image was removed in this condition. Participants therefore saw cigarette packages with the top half consisting of the warning text statement on a black background. We retained the same text size, font style, and positioning as in conditions 1 and 2.

Condition 4—Surgeon General's warning. For the Surgeon General's warning condition, respondents saw the four text-based warnings that are currently used on cigarette packages (black text on a white box background). We placed this warning in a black box covering the top half of the front of the package to control for warning label size. We used each of the four Surgeon General's warnings twice, and we randomly selected the warning *Cigarette smoke contains carbon monoxide* to appear a third time to make a total of nine stimuli (keeping the number of warnings consistent across conditions).

Condition 5—No warning. In Condition 5, participants viewed nine images of the fronts of existing cigarette packages, the way packs currently appear in the marketplace. The current warning labels are placed on the side of the package, so cigarette fronts do not contain visible warning labels.

One assumption is that the warning label conditions represent variations in the extent to which they function to regulate the commercial speech rights of tobacco companies. In order from the most to least extensive regulation, the conditions are: (1) full-color graphic warning labels, (2) black-and-white graphic warning labels, (3) warning text (no graphic image), (4) Surgeon General's warning on the front of the box, and (5) no warning (current front of box).

Measures

We asked participants to respond to a variety of measures on 5-point Likert scales ranging from (1) *strongly disagree* to (5) *strongly agree*.

As a measure of health risk beliefs, we asked participants to indicate their level of agreement with these statements: *I believe that smoking causes heart disease, I believe that smoking causes cancer, I believe that smoking causes health problems, I believe that cigarettes are addictive, I believe tobacco smoke can harm the smoker's children, I believe that cigarettes cause fatal lung disease, I believe cigarettes cause*
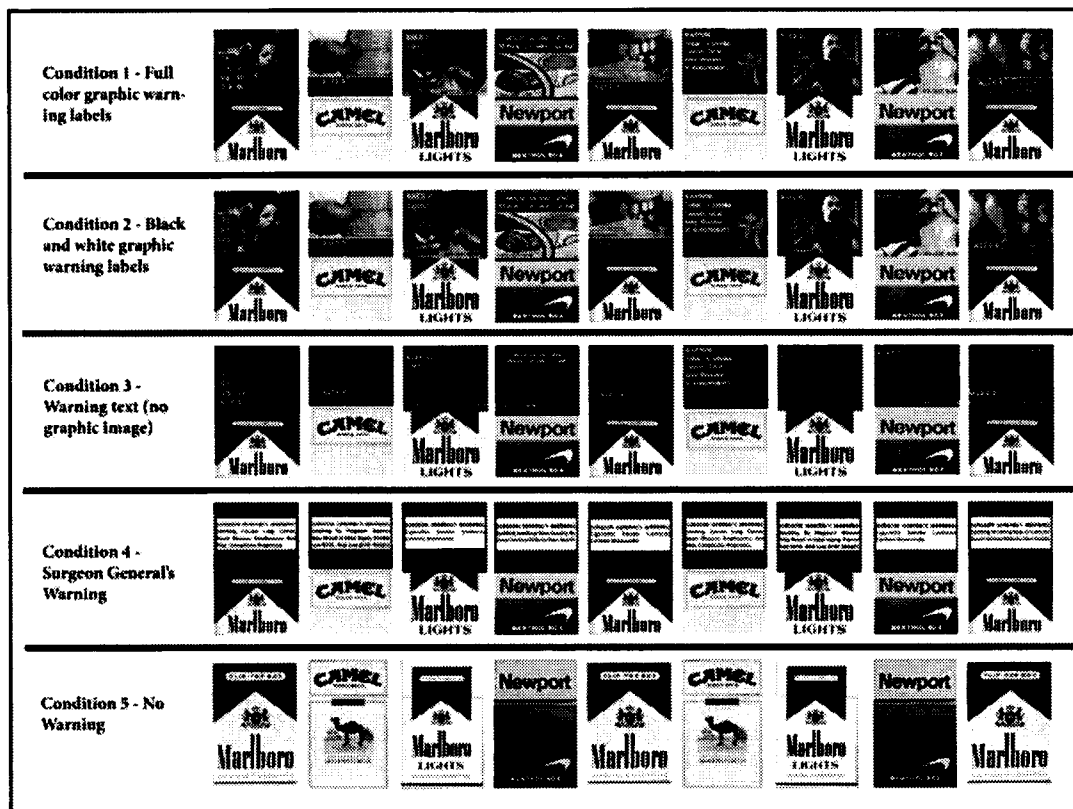
FIGURE 1   Experimental manipulations.

cancer, I believe cigarettes cause stroke and heart disease, I believe that smoking during pregnancy can harm the baby, I believe that smoking can kill you, and Smoking cigarettes at all is a health risk. We averaged the responses to these 11 statements into a scale ($n = 135$; $M = 4.52$, $SD = .55$, $\alpha = .95$).

To measure perceived fear, we assessed participants' level of agreement with three statements: The images I just viewed are frightening; The images I just viewed are scary; and The images I just viewed are disturbing. We averaged these three items into a scale ($n = 135$, $M = 2.89$, $SD = .97$, $\alpha = .88$).

Quitting intentions are not a valid measure of effectiveness in a population where participants do not currently smoke. Therefore, we measured perceived effectiveness, which is a known antecedent of actual effectiveness (Dillard, Shen, & Vail, 2007). We gauged perceived effectiveness by averaging responses to two statements: The images I just viewed are convincing, and the images I just viewed would have the intended effect ($n = 135$, $M = 3.04$, $SD = .77$, $\alpha = .63$).

STUDY 1 RESULTS

The first research question (RQ1) asked whether alternatives to the full-color graphic warning labels, based on less

extensive rules or regulations, are perceived as less effective than full color. With full-color graphic warning labels set as the reference group, we conducted a linear regression on perceived effectiveness. As Table 1 indicates, alternatives based on less extensive regulations are perceived as being less effective than the full-color graphic warning labels, with the exception of the black-and-white graphic warning labels. While the regression coefficient suggests that the black-and-white graphic warning labels are perceived as slightly less effective than the full-color graphic warning labels, this difference is not significant. However, the packages with warning text only (no graphic image), those with the Surgeon General's warning, and the no-warning condition (current box front) are all perceived as significantly less effective than the packages with the full-color graphic warning labels. Furthermore, the means progress downward, such that the less extensive the regulation that the alternative is based upon, the lower the mean. Therefore, in response to RQ2, which asks whether there is a label alternative that is based on a less extensive regulation than the full-color graphic warning label but that is similarly effective, the data provide a preliminary indication that the black-and-white graphic warning label may be worthy of consideration.

Next, we asked whether alternatives to the full-color graphic warning labels, based on less extensive regulations, generate lower levels of health risk beliefs and fear (RQ3).

TABLE 1
Linear Regression Analyses Comparing Full-Color Graphic Warning
Labels With Alternative Warning Label Conditions (Study 1)

	Perceived Effectiveness	Health Risk Beliefs	Fear Perceptions
Full-color graphic warning labels (reference group)	M = 3.41	M = 4.59	M = 3.74
Black-and-white graphic warning labels	M = 3.23 B = −.18 p = .36	M = 4.62 B = .03 p = .86	M = 3.26 B = −.48 p = .03
Warning text (no graphic image)	M = 2.92 B = −.49 p = .02	M = 4.45 B = −.14 p = .37	M = 2.64 B = −1.10 P < .001
Surgeon General's Warning	M = 2.87 B = −.55 p = .007	M = 4.47 B = −.12 p = .41	M = 2.64 B = −1.10 P < .001
No Warning (current box front)	M = 2.77 B = −.65 p = .001	M = 4.49 B = −.10 p = .52	M = 2.13 B = −1.61 P < .001

B are unstandardized coefficients.

p values indicate significant difference from the full-color graphic warning labels.

We conducted separate linear regressions on these two variables, using the full-color graphic warning label condition as the reference group. As Table 1 indicates, there are no significant differences in the level of health risk beliefs generated by the full-color graphic warning labels compared to alternatives. This may be due to a ceiling effect, wherein health risk beliefs are already very high and exposure to package warning labels may not have room to further influence those beliefs. However, in the case of fear perceptions, Table 1 reflects that all alternatives to the full-color graphic warning labels generate significantly lower levels of fear and the means progress downward, with the two text-only conditions (warning text with no graphic image and Surgeon General's warning) having quantitatively equivalent means.

We next tested whether health risk beliefs and fear mediate the relationship between exposure to warning labels (at varying levels of regulatory action) and perceived effectiveness (RQ4). Three steps are necessary to establish mediation. First, there must be a significant relationship between the independent variable (viewing full color versus alternatives) and the potential mediators (health risk beliefs and fear perceptions). Second, potential mediators must be associated with the dependent variable (perceived effectiveness). Third, the indirect effect (the product of the independent variable's effect on the mediator and the association between the mediator and the dependent variable) must be significantly different from zero, as evidenced by a 95% confidence interval that does not overlap zero. Establishing all three steps would allow us to conclude that randomized conditions have an indirect effect on perceived effectiveness via one or both of the proposed mediators.

We already reported step 1 of this process in the preceding. As indicated in Table 1, levels of perceived fear are highest in the full-color warning label condition compared to all other randomized conditions. There is no difference in health risk beliefs across the study conditions. Therefore, while fear remains a potential mediator, health risk beliefs is eliminated from consideration as a mediator

We used ordinary least squares (OLS) regression to predict perceived effectiveness as a function of both health risk beliefs and fear perceptions, $F(2,132) = 23.33$, $p < .001$. Fear perceptions are positively associated with perceived effectiveness ($B = .39$; $p < .001$), indicating that higher perceptions of fear are associated with higher perceived effectiveness of the warning label. Health risk beliefs were negatively associated with perceived effectiveness ($B = -.18$, $p = .086$), although this effect was not statistically significant at traditional significance levels ($p < .05$).

Hayes and Preacher (in press) and Hayes (2013) developed a procedure (MEDIATE) to investigate indirect effects in a model that includes a multi-categorical independent variable and accounts for bias associated with traditional analyses of step 3 for establishing significant mediation. With full-color graphic warning labels set as the reference group, we compared the relative indirect effects of the alternative warning label conditions on perceived effectiveness through the mediators of fear perceptions and health risk beliefs. We kept health risk beliefs in the model to account for any association with perceived fear. The MEDIATE procedure established that the relationship between label condition and perceived effectiveness was mediated by the level of fear perceptions (N of samples = 5,000), but not the level of health risk beliefs. Figure 2 shows the point estimates and confidence intervals (indirect effect confidence intervals that do not overlap with zero can be interpreted as evidence of a significant indirect effect). The difference between full color and the other label conditions is thus mediated by fear, since the residual direct effect of each randomized condition in predicting perceived effectiveness was not statistically significant (all $ps > .39$). In all four cases, the less extensive warning labels (relative to the full-color graphic image condition) produced lower levels of perceived fear, which in turn predicted lower perceived effectiveness. Taken together, our results so far point to the possibility that perceived fear may be a necessary mechanism for reaching the public health benefit that the FDA is seeking, at least in a population of nonsmoking young adults. Next, we test the research questions on a group of self-identified, daily smokers, with the effectiveness measure of behavioral intentions to quit smoking.

STUDY 2 METHOD

The purpose of Study 2 was to apply the approach from Study 1 to a sample of daily smokers. Additionally, we
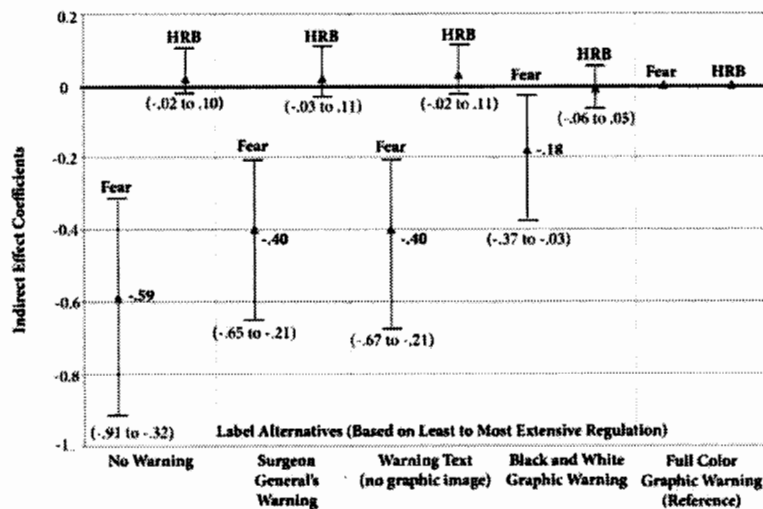
FIGURE 2 Indirect effect comparisons for fear and health risk beliefs (HRB) on perceived effectiveness (Study 1).

replaced the perceived effectiveness outcome measure with a more direct measure of effectiveness, behavioral intentions to quit smoking.

Participants

We recruited 153 participants using Amazon Mechanical Turk (MTurk). Participants confirmed they were daily smokers before they received access to the study and confirmed this again twice during data collection, after they were assured that their compensation would not be forfeited. We paid each participant $1, a large incentive by MTurk standards. We removed six participants from analysis for admitting that they were not daily smokers when asked; we removed one participant for not completing the study in a reasonable amount of time, and one participant for answering in patterned response sets (e.g., answering all 5s to every question even when items were reverse coded). The final sample was 145 daily smokers, who ranged in age from 18 to 67 ($M = 32.84$; $SD = 11.01$); 86 were male and 59 were female. All of these participants confirmed they smoke "every day."

Procedure and Measures

We used procedures in Study 2 identical to those in Study 1, except where noted in the following. All participants responded to questions regarding their current smoking behavior. We then randomly assigned between 28 and 30 participants to view one of the five warning label image conditions from Study 1. Following the presentation of stimuli, participants completed the dependent measures described in the following. We debriefed participants with an IRB-approved electronic debriefing form.

Study 2 used the same warning label manipulations, the same measure of health risk beliefs ($n = 145$, $M = 4.38$, $SD = .64$, $\alpha = .94$), and the same measure of fear perceptions ($n = 145$, $M = 2.80$, $SD = 1.31$, $\alpha = .94$) that were used in Study 1.

To measure behavioral intentions to quit smoking, participants responded to the statement *I will try to quit smoking cigarettes completely and permanently in the next year* ($n = 145$, $M = 3.62$, $SD = 1.27$). While behavioral intentions function as our primary measure of effectiveness in Study 2, we provide some basic analyses for perceived effectiveness (measured the same way as in Study 1; $n = 145$, $M = 2.97$, $SD = 1.07$) in Table 2 for comparative purposes.

STUDY 2 RESULTS

With full-color graphic warning labels set as the reference group, we conducted OLS regression with randomized conditions on behavioral intentions to quit smoking to address RQ1 and RQ2. No significant differences emerged between the full-color labels and all alternatives (see Table 2). There was no evidence to support a total effect of any warning label on intentions to quit smoking.

Next, we conducted separate OLS regressions on perceived fear and health risk beliefs, using full-color graphic warning labels as the reference group (addressing RQ3). As in Study 1, there are no significant differences in the level of health risk beliefs generated by the full-color graphic warning labels compared to alternatives (Table 2). As described earlier, this could be due to a ceiling effect, since the mean health risk beliefs score approached the scale's maximum (as in Study 1). However, in the case of fear perceptions, we observed a pattern similar to Study 1.

TABLE 2
Linear Regression Analyses Comparing Full-Color Graphic Warning Labels With Alternative Warning Label Conditions (Study 2)

	Behavioral Intentions to Quit	Perceived Effectiveness	Health Risk Beliefs	Fear Perceptions
Full-color graphic warning labels (reference group)	$M = 3.62$	$M = 3.22$	$M = 4.42$	$M = 3.83$
Black-and-white graphic warning labels	$M = 3.79$	$M = 3.21$	$M = 4.54$	$M = 3.71$
	$B = .17$	$B = -.01$	$B = .12$	$B = -.11$
	$p = .63$	$p = .97$	$p = .48$	$p = .66$
Warning text (no graphic image)	$M = 3.69$	$M = 3.14$	$M = 4.29$	$M = 2.59$
	$B = .07$	$B = -.09$	$B = -.13$	$B = -1.24$
	$p = .84$	$p = .75$	$p = .46$	$p < .001$
Surgeon General's Warning	$M = 3.76$	$M = 3.02$	$M = 4.46$	$M = 2.53$
	$B = .14$	$B = -.21$	$B = .04$	$B = -1.30$
	$p = .68$	$p = .45$	$p = .79$	$p < .001$
No Warning (current box front)	$M = 3.27$	$M = 2.30$	$M = 4.19$	$M = 1.43$
	$B = -.35$	$B = -.92$	$B = -.23$	$B = -2.39$
	$p = .29$	$p = .001$	$p = .18$	$p < .001$

B are unstandardized coefficients.

p values indicate significant difference from the full-color graphic warning labels reference group.

The mean fear perceptions lower as the alternatives become less extensive (Table 2). However, there is no difference in fear perceptions between the full-color graphic warning labels and the black-and-white graphic warning labels. All other alternatives generate lower levels of fear than full color.

While we did not detect a total effect of labeling conditions on intentions to quit smoking, there remains the possibility of the labeling conditions having an indirect effect on quit intentions via increased perceptions of fear (Hayes, 2013; Hayes & Preacher, in press). To formally test for the possibility of an indirect relationship, we combined the data from two samples of daily smokers (Study 2 and Study 3) to maximize statistical power. The results appear after Study 3 methods and results.

STUDY 3 METHOD

The purpose of Study 3 is to apply the approach from Study 1 and Study 2 to a sample of visually confirmed smokers in a field experiment.

Participants

Research assistants recruited 148 participants from a downtown pedestrian neighborhood near a social services building during business hours after observing them smoking cigarettes. We paid these participants $10 cash in exchange for completing the study. The final sample was comprised of 119 smokers, after we removed participants from the analysis for the following reasons: admitting they were not daily smokers ($n = 12$), appearing visibly distracted or exhibiting signs of illiteracy ($n = 15$), informing the researchers of legal blindness ($n = 1$), and answering in response sets ($n = 1$).

The remaining 119 participants ranged in age from 18 to 66 years ($M = 32.34$, $SD = 11.84$); 75 were male and

44 were female. All of these participants confirmed they smoke "every day."

Procedure and Measures

All participants responded to questions regarding their current smoking behavior. We then randomly assigned participants to view one of the five warning label image conditions from Study 1 and Study 2. We randomly assigned participants to conditions, resulting in between 20 and 27 participants in each condition. Following the presentation of stimuli, participants completed the dependent measures described in the following. We then fully debriefed participants with an IRB-approved electronic debriefing form.

Study 3 used the same warning label manipulations, measure of health risk beliefs ($n = 119$, $M = 4.12$, $SD = .71$, $\alpha = .95$), measure of fear perceptions ($n = 119$, $M = 2.92$, $SD = 1.02$, $\alpha = .88$), and measure of intentions to quit smoking ($n = 119$, $M = 3.39$, $SD = 1.13$) that were used in Study 2. While behavioral intentions function as our primary measure of effectiveness in Study 3, we provide some basic analyses for perceived effectiveness (measured the same way as in Study 1 and Study 2; $n = 119$, $M = 3.25$, $SD = 0.87$) in Table 3 for comparative purposes.

STUDY 3 RESULTS

With full-color graphic warning labels set as the reference group, we conducted an OLS regression of randomized condition on behavioral intentions to quit (addressing RQ1 and RQ2). As Table 3 indicates, no significant differences emerged between the full-color labels and all alternatives. There was no evidence to support a total effect of any warning label on intentions to quit smoking.

TABLE 3
Linear Regression Analyses Comparing Full-Color Graphic Warning Labels With Alternative Warning Label Conditions
(Study 3)

	Behavioral Intentions to Quit	Perceived Effectiveness	Health Risk Beliefs	Fear Perceptions
Full-color graphic warning labels (reference group)	$M = 3.70$	$M = 3.74$	$M = 4.17$	$M = 3.83$
Black-and-white graphic warning labels	$M = 3.28$	$M = 3.14$	$M = 4.05$	$M = 3.31$
	$B = -.42$	$B = -.60$	$B = -.12$	$B = -.52$
	$p = .20$	$p = .01$	$p = .56$	$p = .03$
Warning text (no graphic image)	$M = 3.10$	$M = 3.35$	$M = 3.96$	$M = 2.87$
	$B = -.60$	$B = -.39$	$B = -.21$	$B = -.96$
	$p = .09$	$p = .11$	$p = .33$	$p < .001$
Surgeon General's Warning	$M = 3.63$	$M = 3.46$	$M = 4.41$	$M = 2.57$
	$B = -.07$	$B = -.28$	$B = .24$	$B = -1.26$
	$p = .84$	$p = .22$	$p = .22$	$p < .001$
No Warning (current box front)	$M = 3.17$	$M = 2.58$	$M = 3.95$	$M = 2.08$
	$B = -.53$	$B = -1.16$	$B = -.22$	$B = -1.74$
	$p = .11$	$p < .001$	$p = .30$	$p < .001$

B are unstandardized coefficients.
p values indicate significant difference from the full-color graphic warning labels reference group.

We next conducted separate OLS regressions on perceived fear and health risk beliefs, using full-color graphic warning labels as the reference group (addressing RQ3). Similar to both Study 1 and Study 2, there are no significant differences in the level of health risk beliefs generated by the full-color graphic warning labels compared to alternatives (Table 3). Health risk beliefs were very high across all study conditions (above 4 on a 5-point Likert scale), suggesting a possible ceiling effect.

In the case of fear perceptions, we observed a pattern similar to both Study 1 and Study 2. The mean fear perceptions become progressively lower as the alternatives become less extensive (Table 3). All alternatives, including the black-and-white graphic warning label, generate lower levels of fear perceptions compared to the full-color graphic warning labels.

To address RQ4, we tested whether warning label condition has an indirect effect on behavioral intentions to quit via health risk beliefs and perceived fear. To maximize statistical power, we combined the two samples of daily smokers from Study 2 and Study 3. For step 1 (effects of randomized conditions on proposed mediators), we conducted an OLS regression using the combined dataset ($n = 264$), comparing all alternative conditions (entered as dummy variables) to the FDA full-color reference group. The full-color warning label condition produced greater perceived fear compared to all other conditions except the black-and-white graphic warning label. There was no difference in health risk beliefs by randomized condition. Therefore, as in Study 1, while fear remains a potential mediator, health risk beliefs are eliminated as a possibility.

Next, we test whether each proposed mediator is associated with quit intentions. We used OLS regression to predict quit intentions from health risk beliefs and fear

perceptions, $F(2, 261) = 25.24$, $p < .001$. Both fear perceptions ($B = .20$; $p = .001$) and health risk beliefs ($B = .55$; $p < .001$) were positively associated with quit intentions, indicating that the higher the perceptions of fear and health risk beliefs are, the higher are the reported behavioral intentions.

Next, with the full-color graphic warning label condition set as the reference group, we compared the relative indirect effects of the alternative warning label conditions on perceived effectiveness through the mediators of fear perceptions and health risk beliefs. As in Study 1, health risk beliefs were kept in this model to account for any association with perceived fear. Using the MEDIATE macro (Hayes, 2013; Hayes & Preacher, in press), the data are consistent with an indirect effect of randomized conditions on behavioral intentions via the level of fear perceptions (N of samples $= 5,000$), but not the level of health risk beliefs. Figure 3 shows the point estimates and confidence intervals (indirect effect confidence intervals that do not overlap with zero can be interpreted as evidence of a significant indirect effect). In three of the four cases (all but the comparison between full-color and black-and-white graphic labels), there is evidence consistent with an indirect effect of the less extensive warning label on lower intentions to quit via lower levels of perceived fear. These results reiterate the possibility (consistent with Study 1) that fear is an important mechanism for reaching the public health benefit that the FDA is seeking on a population of adult daily smokers.

GENERAL DISCUSSION

This article tested the effectiveness of alternatives to full-color graphic cigarette warning labels, each featuring
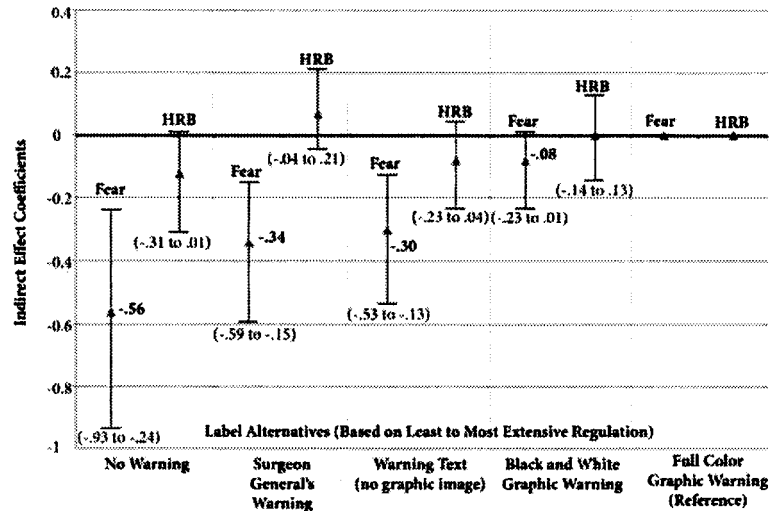
FIGURE 3 Indirect effect comparisons for fear and health risk beliefs (HRB) on behavioral intentions to quit smoking (daily smokers: Studies 2 and 3).

less extensive regulations, across three separate random-ized experiments. Results were generally consistent. By and large, less extensive labels were less effective than the full-color graphic warning labels at generating perceived fear, although there was some evidence that the black-and-white labels were comparable in effectiveness on this outcome. Lower levels of perceived fear, in turn, were associated with lower (perceived and actual) effectiveness. In Study 1, non-smoking young adults perceived the black-and-white graphic warning label condition as comparably effective as the full-color graphic warning level condition, while other conditions were clearly perceived as less effective. At the same time, mediation models indicated that the black-and-white graphic labels generated less perceived fear than the full-color graphic labels, which in turn was associated with lower perceived effectiveness. In Study 2 and Study 3, featuring daily smokers, there were no total effects of label condition on behavioral intentions to quit smoking. Similar to Study 1, however, mediation models indicated that less extensive labels (except for the black-and-white graphic labels) produced less fear than the full-color graphic labels, which in turn was associated with lower intentions to quit smoking. Combined, these findings provide consistent evidence that text-based labeling strategies may be less effective than labels that feature graphic images because the graphic images produce greater levels of fear, a key mediator of intentions to quit smoking.

Theoretical Implications

We also compared two theoretical mechanisms through which warning labels may influence perceived effective-ness and quit intentions. All three studies offered consistent evidence that perceived fear, not health risk beliefs, is an important pathway linking graphic labels to perceived and actual effectiveness. Health risk beliefs were uniformly high across the three studies, suggesting the possibility of a ceil-ing effect—limited room to further increase these beliefs. Combined, these studies consistently suggest that fear may be necessary to advance the compelling government interest.

Feelings of fear can motivate individuals to take actions that will reduce this negative emotional state. In the case of cigarette warning labels, respondents who felt fearful reported higher intentions to quit smoking cigarettes. One theoretical issue worth considering is that health risk beliefs and fear are not opposing factors, but rather two sides of the same coin, with the latter reflecting internalization of health risk beliefs. As noted in the literature review, the EPPM sug-gests that fear is the by-product of two types of risk beliefs: one's perceived susceptibility to, and severity of, a health risk. The EPPM thus suggests that measures of perceived fear may indirectly capture the types of risk beliefs that are most important in promoting a smoker to quit—not just the notion that smoking has health consequences (captured with the index of health risk beliefs), but that those consequences apply to the smoker and thus motivate intentions to avert the risk by quitting.

Legal Implications

Findings from all three study samples suggest that cigarette warning labels may not succeed in increasing health risk beliefs because they are already quite high. Legally, how-ever, labels may still be required to maintain a standard of factual and informational content. Nevertheless, if per-ceived fear is a necessary mechanism for label effectiveness, a key legal question raised by this work is whether or not

At the same time, questions remain about the extent to which cigarette warning labels could increase health risk beliefs beyond already high levels. Our findings suggest that graphic warning labels may be effective by emphasizing, in a way that is difficult to ignore, the fear-inducing consequences of smoking. The value and constitutional merit of reminding individuals about what they already know, in a way that promotes fear, may be a key legal debate in the future. For example, must the health risk messages communicate a more accurate understanding of the health risks of smoking, or can they viscerally remind individuals of what they already know? Additionally, what does it really mean to "inform" if fear is conceptualized, as noted earlier, as a product of severity and susceptibility, which are informative constructs? Future scientific and legal research should consider this question with respect to the boundaries of the *Central Hudson* doctrine. Should the boundaries of *Central Hudson* be held at "informing" the public in regard to a compelling government interest, or can they be extended to "persuading" the public?

Regulatory Implications

These three studies also have key regulatory implications. As noted earlier, the FDA is currently reworking the labels, and it is important that the FDA keep in mind the potential importance of fear as a mechanism through which behavioral intentions to quit can be achieved. Additionally, it should consider the possibility of a ceiling effect around health risk beliefs. It is likely the FDA will once again have to defend its warning-label selections in court. The legal arguments and implications outlined in the preceding, as well as accumulated research findings on the attributes and mechanisms of label effectiveness, are likely to be key points of discussion. This article suggests that the FDA could consider the black-and-white graphic warning label condition as a less extensive alternative to the full-color labels, since differences between these two conditions were minimal. As noted earlier, one requirement of *Central Hudson* is that the regulation not be more extensive than necessary to achieve its intended effect. Since the full-color warning label and the black-and-white warning label conditions generated comparable levels of fear in Study 2 (but not Studies 1 and 3), which produced comparable indirect effects on intentions to quit smoking, it is possible that the black-and-white warning labels may represent a less extensive measure.

Limitations

While these three experiments replicate similar patterns of relationships with three different experimental groups, some limitations are worth clarifying. The first study featured young adult nonsmokers. This participant group may remain vulnerable to smoking uptake (Moran, Wechsler, & Rigotti, 2004; Morley, Hall, Hausdorf, & Owen, 2006). However, the fact that the message did not directly relate to their own smoking behavior is a limitation of Study 1, and the reason we conducted Study 2 and Study 3 among adult daily smokers. Nevertheless, the consistency of findings across the three studies suggests that nonsmokers respond to graphic and textual warning labels in ways that are similar to those who smoke every day.

Another limitation involves the use of the MTurk sample for Study 2. While we checked for duplications, it is possible that individuals used different MTurk worker IDs to take the study more than once. Finally, while we cannot visually confirm smoking behavior with the MTurk sample, we had three different checks in place to confirm that they were, indeed, daily smokers.

We were able to visually confirm smoking behavior in Study 3, but we did not measure the socioeconomic characteristics of the sample. As noted earlier, we also had to remove several participants due to limited literacy, resulting in lower sample sizes. Since findings were comparable to Study 2, we collapsed Studies 2 and 3 for the mediation analyses, but optimally we would have replicated these analyses separately across all three samples.

Each of our label conditions featured the same high level of image quality (same resolution and size). In the warning text (no graphic image) condition, the image was simply removed, leaving the text exactly in the position it would otherwise be. While this permitted us to isolate just the influence of removing the image, one limitation of the study is that this particular condition could have seemed less authentic as an actual label. This is because without the image the spacing of the text may have seemed unusual or as though something were missing.

All three studies asked participants to report on their own behavior. It is thus possible that social desirability may have been a factor. That said, the fact that we observed similar relationships across three different samples, one of which (MTurk) utilized data collection procedures that ensured anonymity (except for a worker ID number), suggests it is unlikely that this factor played a large role in influencing their responses. Finally, another limitation of these studies is that we did not measure the racial breakdown or income level of our three samples. Based on our own informal observations, and knowing the demographics of the populations from which respondents were sampled, it is likely that the college-student sample had a demographic composition

very different from the visually confirmed sample of adult smokers.

Conclusions

We investigated alternatives to full-color graphic warning labels on cigarette packages in three separate randomized experiments. Variations in warning label use of color, graphic images, and text warnings did not influence health risk beliefs but did predict variability in perceived fear. Results were consistent with an indirect effect of graphic warning labels on key outcomes. Graphic warning labels produced greater fear perceptions than text-only warnings and a no-label control group. Perceived fear, in turn, was associated with increased perceived effectiveness and intentions to quit smoking. We conclude that fear seems to be a key mechanism in understanding the types of warning labels that are likely to be effective. These results raise new questions about how best to balance the compelling government interest to encourage smoking cessation with the legal requirement to achieve these interests with the least extensive regulation.

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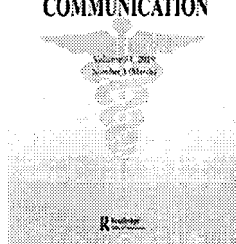
Effects of Varying Color, Imagery, and Text of Cigarette Package Warning Labels among Socioeconomically Disadvantaged Middle School Youth and Adult Smokers

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Effects of Varying Color, Imagery, and Text of Cigarette Package Warning Labels among Socioeconomically Disadvantaged Middle School Youth and Adult Smokers

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ABSTRACT
The U.S. Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) of 2009 paved the way for the Food and Drug Administration (FDA) to propose nine different graphic warning labels (GWLs) intended for prominent placement on the front and back of cigarette packs and on cigarette advertisements. Those GWLs were adjudicated as unconstitutional on the ground that they unnecessarily infringed tobacco companies' free speech without sufficiently advancing the government's public health interests. This study examines whether less extensive alternatives to the original full-color GWLs, including black-and-white GWLs and text-only options, have similar or divergent effects on visual attention, negative affect, and health risk beliefs. We used a mobile media research lab to conduct a randomized experiment with two populations residing in socioeconomically disadvantaged communities: biochemically confirmed adult smokers (N = 313) and middle school youth (N = 340). Results indicate that full-color GWLs capture attention for longer than black-and-white GWLs among both youth and adult smokers. Among adults, packages with GWLs (in either color or black-and-white) engendered more negative affect than those with text-only labels, while text-only produced greater negative affect than the packages with brand imagery only. Among youth, GWLs and text-only labels produced comparable levels of negative affect, albeit more so than brand imagery. We thus offer mixed findings related to the claim that a less extensive alternative could satisfy the government's compelling public health interest to reduce cigarette smoking rates.

The 2009 U.S. Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) sought to inform Americans of the health risks of smoking, prevent uptake of cigarette smoking in youth, and lower smoking rates among adults. The Act paved the way for the Food and Drug Administration (FDA) to propose nine different GWLs intended for prominent placement on the front and back of cigarette packs and on cigarette advertisements. Major tobacco companies (TCs) took to court several concerns about the proposed graphic warning labels, arguing that the labels were both too extensive and ineffective in raising awareness of health risks associated with smoking. After a federal appeals court ruled in favor of these TCs, the FDA decided against pursuing further review in the Supreme Court, opting instead to revisit the content of the labels. To date, the FDA has not yet proposed new warnings.

Using eye-tracking technology and self-reported reactions to cigarette packs with varied warning labels, this study examines the TCs claim that a less extensive regulation, such as a warning with black-and-white (B&W) image or featuring only text, could satisfy the government's public health interest of reducing smoking rates. We focus on two populations from disadvantaged socioeconomic settings: biochemically confirmed adult smokers

and middle school youth. Smoking rates are higher among those living below the poverty level (26%) compared to those at or above it (14%; Centers for Disease Control and Prevention, 2016). In addition, 3,200 people try their first cigarette each day, and 9 of 10 people who become regular smokers try their first cigarette by age 18 (US Department of Health and Human Services (USDHHS), 2012). These populations share disproportionate burdens of tobacco use and are underrepresented in tobacco research.

Legal precedent and competing arguments

The U.S. Congress delegated regulatory authority over tobacco products to the FDA when it enacted the Tobacco Control Act in 2009 (H.R. 1256). The Tobacco Control Act specified that the FDA "shall issue regulations that require color graphics depicting the negative health consequences of smoking" (H.R. 1256, Division A, Title 2, Sec. 201(d)), specifying that the warnings would be in full color and cover the top 50% of both sides of cigarette boxes.

In 2011, the FDA released a set of nine warnings, following the presentation of draft warnings and a period of public comment. Major TCs immediately objected to the new warnings, arguing the

warnings extensively infringed on their right to market a legal product, specifically taking issue with the presence of a full-color image on the warning (in R.J. Reynolds Tobacco Company et al. vs. United States Food and Drug Administration, 2011). Drawing on the Central Hudson test (Central Hudson Gas & Electric Corp. vs. Public Service Commission, 1980), TCs argued that any warning requirement should be no more extensive than necessary to achieve the government's interest, implying that the proposed warnings were too extensive.

In 2012, the TCs won the case in the trial and appeals courts, and the U.S. government decided to reassess the labels rather than seek further legal review in the Supreme Court. The FDA remains under pressure to release new labels. In October 2016, the American Academy of Pediatrics and seven other medical and public health groups filed suit against the FDA, claiming that the number of smokers in the United States could have been reduced by millions in the time the FDA has taken to review the labels (Jenco, 2016). This underscores the need for communication researchers, policy analysts, and legal scholars to provide additional insights about the content and effectiveness of various warning label options that might satisfy the compelling government interest test while maintaining free speech protections. That test requires the government to show that a challenged regulation is the least restrictive means of achieving a compelling interest.

The U.S. government and TCs can be expected to differ both on what constitutes a compelling government interest and the least restrictive means of advancing that interest. The FDA argues that text-only warnings do not attract and hold attention at the same level as warnings with images and that warnings with imagery serve to inform potential smokers of the risks associated with smoking as well as support intentions of smokers who may want to quit (75 Fed.Reg. 69,524, 2010). The argument implicitly contends that even if people understand the health risks of smoking cigarettes, they may need reminders to make those risks salient.

TCs focus their arguments on whether the labels increase knowledge by informing people of smoking's health risks. They claim the government lacks a compelling interest in informing people of health risks associated with smoking, because people already know that smoking is harmful. Therefore, new warning labels will fail to change knowledge of smoking risks (R.J. Reynolds Tobacco Company et al., vs. United States Food and Drug Administration, 2011, Document 18, p. 23). TCs further argue that people already overestimate the risks associated with smoking (Schneider, Gadinger, & Fischer, 2012) and that graphic warning labels are a government-imposed "emotionally charged anti-smoking message" (R.J. Reynolds Tobacco Company et al. vs. United States Food and Drug Administration, 2011, doc 18, p. 14).

Communication theory and smoking behaviors

The message impact framework (Noar et al., 2016b) provides a lens for understanding the factors contributing to warning label effects. Our study examines whether variations in the use of color and graphic imagery influence key predictors of smoking behavior, including (1) visual attention, (2) negative emotional reactions, (3) health risk beliefs, and (4) quit intentions (among adult

smokers) or smoking susceptibility (among youth). We focus particular attention on the role of negative emotional reactions in this process.

The idea that GWLs are nothing more than a government-imposed "emotionally charged message" runs against much of what has been discovered in the fields of communication, marketing, and psychology. Decades of research has tested the effectiveness of arguments and peripheral cues in shaping the persuasiveness of strategic messages (O'Keefe, 2002) as well as the important role of emotion in information processing (Slovic, Finucane, Peters, & MacGregor, 2004). Side by side with factual text claims, many of the format elements at issue (e.g., size, color, and placement) function as cues to encourage attention to messages and feature emotional appeals (e.g., fear, guilt) to aid in deeper processing and motivation (Evans et al., 2015; Peters, Lipkus, & Diefenbach, 2006). To this end, some legal scholars agree that emotion and reason are connected processes and that therefore emotionally evocative messages are not inherently problematic for the U.S. government to compel, as long as the messages are not misleading or erroneous (Corbin, 2014; Tushnet, 2014). TCs also rely on cues and emotional appeals in their own marketing and packaging, understandably so because human beings rely on cues in the environment to sift through a bombardment of stimuli to determine what is appealing, status-enhancing, important, useful, or threatening (Slovic et al., 2004). Once a stimulus is attended to, emotion is a key component of information processing, memory, and decision making.

Evidence of cigarette package warning label effectiveness

Scientific consensus is building that improved warnings on the U.S. cigarette packs will likely function as intended. In two systematic reviews of dozens of studies, the authors concluded that strengthened warnings (i.e., improved text, implemented graphic warnings, or enhanced graphic warnings relative to weaker versions) increased several key variables that are the foundations of future behavioral change: attention to the warnings, recall of their key messages, negative affect, perceived effectiveness, knowledge about smoking, increased quit attempts, and decreased smoking prevalence (Noar et al., 2016a, 2016b). Brewer et al. (2016) recently reported results from a randomized clinical trial in which researchers added, each week, either (a) a pictorial warning label to the top half of the cigarette pack, or (b) the existing Surgeon General's warning label to the side of each cigarette pack. Smokers exposed to pictorial warnings had a 6% increase in quit attempts over those exposed to the text-only warning (40% vs. 34%). Pictorial warnings appeared to work by increasing warning-related thoughts, thoughts about smoking harms, and negative emotions.

Combined, the meta-analyses and controlled field trial make a compelling argument that graphic warning labels can increase quit-related knowledge, emotions, intentions, and behavior among adult smokers. It is yet unclear, however, whether less restrictive versions of these labels may have comparable effects, whether these effects transfer to youth, or whether smokers from socioeconomically disadvantaged communities respond differently to such warnings.

Graphic warnings and socioeconomic status

As noted above, rates of cigarette smoking in the United States vary by socioeconomic status. Although smoking rates have declined in the past several decades (Centers for Disease Control and Prevention, 2016), the rate of decline has not been evenly distributed. Only 7% of Americans with a college degree smoked in 2015, versus 24% of those without a high school diploma and 34% of those with a graduate equivalency diploma (GED) (Centers for Disease Control and Prevention, 2016).

Previous research suggests that graphic, novel, and emotional cues in warning messages about cigarette smoking may be particularly important for those with less education and at lower income levels, because they grab attention, are more memorable, are easier to process, stimulate more discussion, and are harder to ignore than textual arguments (Durkin, Brennan, & Wakefield, 2012; Ramanadan, Nagler, McLoud, Kohler, & Viswanath, 2017; Thrasher et al., 2012). Studies have yet to test, with a socioeconomically disadvantaged population, whether warnings with full-color images are more effective than black and white images and, similarly, whether an equally prominent text-only warning could promote similar levels of visual attention and negative affect as a warning with an image.

Graphic warnings and youth

Although cigarette smoking is declining among adolescents, an estimated 1 in 20 youth between the ages of 12-17 have smoked a cigarette in the last 30 days. Nearly half of adult smokers became regular, daily smokers before age 18 (USDHHS, 2012). Despite being a primary target of tobacco control efforts, youth have been featured far less frequently than adults in GWL research. Indeed, a review of observational studies found only 12% focused solely on youth or adolescents (Noar et al., 2016b). Still, the available evidence suggests that GWLs may be effective at reducing positive smoking beliefs and susceptibility to smoking among youth.

Early studies found that the existing Surgeon General's warning did not convey specific health concerns to youth, who were unable to accurately recall textual warnings in general (Fischer, Krugman, Fletcher, Fox, & Rojas, 1993). More recent studies show that the depth of processing for text-only labels is low (Moodie, MacKintosh, & Hammond, 2010). Cues such as graphic images can attract attention and evoke emotional reactions in youth who are otherwise unable or unmotivated to process health messages (Keys, Morant, & Stroman, 2009). Teens spend more time looking at pictorial warnings than text-only warnings (Peterson, Thomsen, Lindsay, & John, 2010), and gaze duration predicts recall for pictorial warnings but not text-only warnings. Youth perceive pictorial warnings on cigarette packs as more effective than text-only warnings (Vardavas, Connolly, Karamanolis, & Kafatos, 2009), particularly when they contain graphic disease depictions (Hammond et al., 2012).

Several studies have looked at reactions to the proposed FDA warnings. One found that youth perceive full-color (FC) versions of these warnings as more effective than those in B&W

(Hammond, Reid, Driezen, & Boudreau, 2013). Another study concluded that the proposed FDA warnings elicit strong negative emotions and cognition among both youth and adult smokers (Nonnemaker, Choiniere, Farrelly, Kamyab, & Davis, 2015). A third, brain imaging study found evidence that viewing the proposed warnings lowered smoking cravings among adolescent smokers (Do & Galván, 2014). None of these studies, however, have systematically compared the effects of graphic FC, graphic B&W, text-only labels of similar size conveying the exact same verbal content or the long-standing Surgeon General's Warnings (SGWs) on visual attention, negative affect, and health risk beliefs, or whether these effects manifest themselves among youth from socioeconomically disadvantaged communities, one of the primary goals of the current paper.

Methods

Because the U.S. government may not compel more speech than necessary to achieve its interests—here, the interest in public health—our studies compare how exposure to less extensive alternatives to the full-color graphic warnings proposed by the FDA influences specific outcomes proposed in the message impact framework. With these considerations, we offer two randomized experiments with two different, socioeconomically disadvantaged populations named as key considerations in the Tobacco Control Act: adult smokers and middle-school youth. We manipulate features of the messages that TC's argued compelled speech beyond the point of public health benefits, particularly the use of a full-color image in addition to new text, holding the size (50% of the package) and placement of the warning (the top half) constant to avoid confounding the impact of warning label content features with size). The Institutional Review Board (IRB) of the authors' institution approved all study protocols and procedures.

Recruitment procedures and study participants

Adults

Adult participants (N = 313) resided in both rural and urban areas of the Northeastern United States. We identified low SES communities by a combination of analysis of median annual household income census data with attention to areas under $35K, contact with site-specific organizations that served low-SES communities, discussions with local representatives, and in-person site scouting. We visited each site only once, unless it was a large urban area, in which case up to three different parts of a given city served as data collection sites.

We first secured permits and necessary security in each community and, when possible, formed partnerships that met University IRB protocols. On data collection dates for adults, we arrived in city and town centers or at a host organization's location with a fully functional mobile laboratory (the size of a small RV) equipped with five private experimental workstations. We placed signage around the lab, indicating that adults who were regular smokers could participate in the study for $20 cash. If we had a host, that host would let their clientele know about our presence via Facebook, fliers, and word of mouth. Data collection most often occurred between 9am and 6pm. After obtaining informed consent, we confirmed participants as regular smokers through one of two biochemical validation procedures: (a) a CoVita

carbon monoxide detection breath test requiring at least 7 ppm (a result indicating regular smoking) or, in a handful of people with self-proclaimed breathing problems, (b) an Alere saliva test indicating a positive rating for the presence of cotinine (a nicotine metabolite). We only allowed qualifying participants to continue.

The adult sample identified as 64% male, 10% Hispanic, and 38% as non-White (n = 83 Black; n = 38 one or more non-White, non-Black categories). A majority (73%) had a total yearly household income of <$20,000/year, 67% reported their highest level of formal education being a high school diploma or less, 71% reported having utilized government food voucher services, and 59% reported being food insecure.

Youth

Youth participants (N = 340) were middle school students living in both rural and urban communities in the northeastern United States. We first identified communities via census data and contacts with partner organizations. We then reviewed publicly available data on the percentage of students who qualified for the federal free or reduced lunch program for low-income families. We completed district-level approval and permissions processes as required, and then approached qualifying schools (those with between 40% and 100% of students receiving free or reduced-price lunch) for permission to conduct the study with 6th to 8th grade students during school hours. Participating schools sent parents IRB-approved, opt-out consent forms in the weeks before we conducted the study, and each participant signed an assent form immediately before taking the study. Middle school students were not required to be smokers to participate.

Half (50%) of the youth respondents who provided information about gender identified as female, 44% as male, 3% "preferred not to answer," and another 3% did not respond. Participants had a median age of 12.6 (SD = 1.0; range 11–14). The majority (63%) identified as non-Hispanic White, 21% Black or African American, 12% Hispanic or Latino, 3% Native American, 2% Asian, and 13% another race or ethnicity. More than half (53%) reported living with a smoker, and 8% had tried at least a puff of a cigarette.

Study procedures

We assigned all participants a unique identifying number that contained details on their random assignment to one of five experimental conditions. We then escorted the participant into a private study station housed in the mobile laboratory and seated them for the study. Each station featured TobiiStudio eyetracking software and Tobii LCD monitors to unobtrusively collect data on the screen location of participants' eye gaze, as well as an iPad with the Qualtrics-based post-test questionnaire. Before viewing the stimuli for their randomized condition, each participant completed a nine-point, eye-tracking calibration process. Research assistants read the study instructions to participants, while those instructions were also visible on the screen. Participants completed all calibration tasks and viewed the images assigned to their condition while seated approximately two feet from the computer monitor.

Immediately after viewing the stimuli according to their assigned condition, we handed respondents an iPad to answer a series of closed-ended questions gauging emotional and cognitive reactions on a Qualtrics survey application. The average participant completed the study in 25 min, not including wait time. We paid each adult participant $20 cash upon study completion. For youth, we offered two incentive options to accommodate district policies and requests: $10 gift cards for students or a $10 per-student payment to the school to support student initiatives. The study took, on average, 15–20 min to complete, and students rarely had to wait to begin the study. We debriefed all participants about the rationale for the study.

Design and stimuli

As noted above, we randomly assigned participants to one of five conditions in which all participants viewed images of cigarette boxes depicting (1) FDA graphic full-color warnings (graphic FC), (2) FDA graphic black-and-white warnings (graphic B&W), (3) new FDA text-only warnings, (4) SGW text-only, or (5) brand-only control (see Figure 1). Each participant viewed a set of nine images of cigarette boxes, randomly ordered, consistent with their condition. The images appeared one at a time, automatically advancing after 10 s each, for 90 s of total screen time. An "X" appeared on the screen in one of nine possible locations in between images to reset the participant's gaze. The images depicted the front of cigarette boxes for the three most popular brands (Marlboro, Camel, and Newport) and for all conditions (except the brand-only control) featured a warning label placed prominently on the top 50% of the pack. Each brand appeared three times in the rotation of nine warnings; we rotated brands across warnings to prevent order effects and so that no one warning was consistently associated with any one brand. The graphic FC and graphic B&W conditions featured verbatim text and images from the FDA's nine warning labels proposed in 2011 with two exceptions. First, we modified the font on some labels to enable us to keep the font size and type consistent across conditions. Second, we omitted the 1-800-QUIT-NOW quit line number that was a part of the original FDA labels but was a source of controversy in litigation (R.J. Reynolds Tobacco Company et al. vs United States Food and Drug Administration, 2011). The new FDA text-only condition featured the same text from the graphic conditions but with the image removed and the text centered on a black background for aesthetic appeal. The SGW text-only condition rotated verbatim text (also on a black background) from the four warnings that are currently mandated on all cigarette boxes in the United States.

Dependent variables: eye tracking measures

Visual attention: gaze duration

We captured visual attention to specific areas of interest (AOIs) on the cigarette packs with eye-tracking technology. We used the Tobii T60XL 24" monitor (1920 × 1200 native resolution) with built in eye-trackers connected to computers with TobiiStudio 3.4.4 eye tracking software installed. We seated

Figure 1. Experimental stimuli in each of the five conditions. *Note:* We rotated the order and warning/brand combination of brands within conditions.

participants such that cigarette pack images were at a viewing distance of approximately 64 cm, decisions meant to replicate the angle and distance of holding a pack at arms-length. We instructed participants to keep their eyes on the screen for all images. We focused our analysis on the duration of fixation in three different AOIs (measured in seconds summed across all nine images): (a) brand logo (on the bottom 50% of the pack for noncontrol participants; the entire image for brand-only control participants), (b) warning (the top 50% of the pack for noncontrol), and (c) graphic pictorial images (for the conditions featuring images, graphic FC and graphic B&W).

Dependent variables: self-reported measures

After viewing the stimuli, participants completed a post-test questionnaire assessing self-reported affective and cognitive responses to the images. We randomized all measures within blocks and all blocks within the questionnaire except for emotional reactions, which we assessed first, and demographics, which we assessed last. We adapted all youth items from previous measures (described below) for potential low-literacy youth (targeting a 4th grade reading level).

Negative affect

We gauged emotional reactions immediately after viewing the stimuli using a set of eight items adapted from the Positive and Negative Affect Schedule (PANAS) (Watson & Clark, 1999). Participants responded to the prompt, "After looking at the pictures of cigarette packs, I felt..." [*afraid, angry, annoyed, sad, disturbed, grossed-out, scared,* and *guilty*] (randomly ordered). Response choices ran from 1 = *not at all* to 5 = *extremely.* Emotion items were highly correlated (average adult r = .69, average youth r = .51) and a single-factor, confirmatory factor model had acceptable fit (adults, CFI = 0.99, SMRR = 0.03; youth, Confirmatory Fit Index (CFI) = 0.96, Standardized root mean squared residual (SRMR) = 0.04), allowing us to treat negative affect as a unitary construct. We therefore averaged the items into a single scale (adults: α = .91, M = 2.12, SD = 1.00; youth: α = .84, M = 2.23, SD = .91).

Old risk beliefs, adults

We assessed health risk beliefs associated with both the old SGWs and the new FDA-proposed warnings using measures adapted from the Population Assessment of Tobacco and Health (PATH) survey (Hyland et al., 2016). We measured four items deemed "old risk beliefs" because their content

(explicit or implied) has been a part of SGW content for decades. We worded these items as follows: "Based on what you know or believe, does smoking cigarettes cause... [babies to be born with low birth weight from the mother smoking during pregnancy, heart disease in smokers, lung cancer in smokers, and lung disease, such as emphysema, in smokers]? We offered participants the response choices of Yes, No, and Not sure. We calculated an old risk belief index by first dichotomizing responses indicating Yes = 1 versus any other response = 0, and then totaling the number of "yes" responses across the four items (range 0–4, M = 3.61, SD = 0.91).

Old risk beliefs, youth

We measured four items among youth (adapted from PATH, Hyland et al., 2016), asking, "Do you believe cigarette smoking is related to... [cancer, lung disease, and heart disease, and problems in babies whose moms smoke]? Response choices ranged from 1 = definitely not to 4 = definitely yes. We calculated the old risk belief index by dichotomizing responses indicating definitely yes = 1 versus other responses = 0 and totaling the number of "definitely yes" responses across the four items (range = 0–4, M = 3.1, SD = 1.4).

New risk beliefs, adults

In addition, we assessed the health risk beliefs associated specifically with the new FDA-proposed labels that were not explicit or implied in any of the existing Surgeon General's Warning labels (also adapted from PATH, Hyland et al., 2016). Items for adults included: "Based on what you know or believe, does smoking cigarettes cause... [children to have breathing problems from secondhand smoke, lung disease in nonsmokers from secondhand smoke, stroke in smokers, and mouth cancer in smokers]. The response choices were Yes, No, and Not sure. We calculated a new health risk belief index by adding the number of responses for which respondents answered "yes" across the four items (range = 0–4, M = 3.32, SD = 1.04).

New risk beliefs, youth

We measured five items among youth (adapted from PATH, Hyland et al., 2016), for three of them asking, "do you believe cigarette smoking is related to... [health problems in non-smokers, stroke, and hole in the throat], as well as two related items posed as questions: Can smoking cigarettes kill you?, and Are cigarettes very addictive? Response choices ranged from 1 = definitely not to 4 = definitely yes. We again calculated a new health risk belief index by adding the number of responses for which respondents answered "definitely yes" across the five items (range = 0–5, M = 3.81, SD = 1.18).

Intentions to quit, adults

We measured quit intentions with three items adapted from the National Adult Tobacco Survey (Centers for Disease Control and Prevention, 2015):Do you want to quit smoking cigarettes for good? [Yes/No]; Do you have a time frame in mind for quitting? [Yes/No], and do you plan to quit smoking cigarettes for good... (In the next 7 days, In the next 30 days, In the next 6 months, In the next year, More than 1 year from now)? We created a dichotomous measure with planning to quit smoking in the next 6 months or earlier coded as "1"

(22%) and not planning to quit, not having a time frame in mind, or planning to quit smoking in >6 months coded as "0."

Susceptibility to smoke, youth

We gauged middle-school youth's susceptibility to smoking using following five items, adapted from validated instruments developed by Pierce, Choi, Gilpin, Farkas, and Merritt (1996) and Jackson (1998): Do you think that... you will smoke a cigarette soon?, you will smoke a cigarette in the next year?, you will be smoking cigarettes in high school?, in the future you might try a cigarette?, And if one of your best friends offered you a cigarette would you smoke it? Response choices ranged from 1 = definitely not to 4 = definitely yes. We considered youth who answered anything other than "definitely not" to any question as susceptible to smoking. This process deemed 42% of the sample as susceptible.

Control variables and analytic approach

Adults

We measured a variety of factors known to predict quit intentions, including levels of nicotine dependence using the Fagerstrom Test for Nicotine Dependence (Fagerström, 2012), and past quit attempts (in the past 12 months; Table 1). We assessed the impact of various warning label conditions on key dependent variables (DVs) using two methods: examining overlap of 95% confidence intervals between conditions (Table 2) and using multivariable models (ordinary least squares (OLS) or logistic regression, depending on the DV's level of measurement) to test for differences from the graphic FC condition while accounting for potential nonrandom assignment of demographics and risk factors (Table 3).

Table 1. Respondent demographics.

	Means (SD) or N's (valid %)	
	Study 1—Adults	Study 2—Youth
Age	M = 39.95 (13.27)	M = 12.57 (1.01)
Gender		
Male	198 (64.3%)	150 (45.3%)
Female	108 (35%)	171 (51.7%)
Prefer not to say	2 (0.6%)	10 (3%)
Hispanic	30 (9.8%)	41 (12.1%)
Race		
White	217 (69.3%)	216 (63.5%)
Black	83 (26.5%)	72 (21.2%)
Other	38 (12.1%)	59 (17.4%)
Smoking variables		
Nicotine dependence (range 0–10)	M = 5.39 (2.34)	–
Tried to quit in past 12 months	169 (54.5%)	–
Live with a smoker	–	181 (53.2%)
Tried a cigarette	–	28 (8.2%)
Respondent is colorblind	33 (10.7%)	24 (7.1%)
Income (Total yearly household)		
$0–$9,999	135 (44.4%)	–
$10,000–$19,999	88 (28.9%)	–
$20,000+	81 (26.6%)	–
Education		
High school graduate	190 (61.7%)	–
College graduate	26 (8.4%)	–
Benefits program recipient		
Emergency food	184 (59.7%)	–
WIC	52 (16.9%)	–
SNAP	220 (71.4%)	–

Note. N = 313 for adults. N = 340 for youth. Percentages are based on the number of respondents with non-missing data for that variable.

Table 2. Means and confidence intervals of dependent variables by condition.

Adults

	Fixation on Brand	Fixation on Warning	Fixation on Image	Negative Affect	New Risk Beliefs	Old Risk Beliefs	Intention to Quit	n =
Graphic FC	14.1 [11.7–16.5]	46.0 [41.7–50.4]	25.2 [22.3–28.2]	2.68 [2.41–2.94]	3.54 [3.31–3.77]	3.59 [3.36–3.82]	.21 [.11–.31]	61
Graphic B&W	16.1 [12.4–19.9]	38.0 [33.5–42.6]	19.1 [16.5–21.7]	2.49 [2.26–2.72]	3.47 [3.24–3.70]	3.78 [3.58–3.98]	.20 [.10–.30]	64
New FDA Text Only	17.9 [14.6–21.2]	40.5 [35.4–45.7]	–	2.01 [1.74–2.27]	3.26 [2.96–3.55]	3.60 [3.37–3.82]	.21 [.11–.31]	62
SGW Text Only	22.9 [18.7–27.2]	33.6 [29.0–38.1]	–	1.89 [1.68–2.10]	3.20 [2.96–3.45]	3.59 [3.39–3.80]	.25 [.14–.36]	64
Brand Only	53.9 [48.0–59.8]	–	–	1.54 [1.36–1.72]	3.15 [2.84–3.45]	3.47 [3.18–3.75]	.24 [.14–.34]	62

Youth

	Fixation on Brand	Fixation on Warning	Fixation on Image	Negative Affect	New Risk Beliefs	Old Risk Beliefs	Intention to Quit	n =
Graphic FC	16.9 [14.9–18.9]	42.6 [39.4–45.7]	25.0 [22.8–27.1]	2.25 [2.04–2.47]	3.93 [3.64–4.21]	3.00 [2.65–3.35]	.43 [.31–.55]	69
Graphic B&W	15.6 [13.4–17.7]	38.9 [34.7–43.1]	21.0 [18.3–23.7]	2.37 [2.14–2.60]	3.91 [3.61–4.21]	3.24 [2.91–3.57]	.41 [.29–.53]	68
New FDA Text Only	18.2 [15.5–20.9]	36.6 [32.9–40.4]	–	2.36 [2.12–2.61]	4.05 [3.79–4.30]	3.25 [2.95–3.57]	.38 [.26–.50]	65
SGW Text Only	17.4 [15.4–19.5]	38.1 [34.7–41.5]	–	2.37 [2.14–2.60]	3.67 [3.39–3.95]	3.25 [2.94–3.57]	.42 [.30–.54]	67
Brand Only	53.3 [49.0–57.5]	–	–	1.82 [1.66–1.98]	3.56 [3.26–3.86]	2.96 [2.60–3.31]	.44 [.32–.56]	71

Note: Cells report the total fixation duration in seconds across all nine packs. FC = Full color; B&W = Black and white; FDA = Food and Drug Administration; SGW = Surgeon General's warning.

Youth

In addition, we measured several known predictors of smoking susceptibility, including previous smoking behavior (*Have you ever tried smoking a cigarette, even one or two puffs?* 8% answered *"yes"*), sensation seeking (using three items of a scale adapted for youth by Jensen, Weaver, Ivic, & Imboden, 2011; α = .78, M = 2.04, SD = .78), and whether anyone living in their home smoked cigarettes (53%; measure adapted from Centers for Disease Control and Prevention, 2014; see Table 1). As with adults, we assessed the impact of various warning label conditions on key DVs by examining overlap of 95% CIs between conditions (Table 2) and using multivariable models (OLS or logistic regression, depending on the DV's level of measurement) to test for differences from the graphic FC condition while accounting for potential nonrandom assignment of demographics and risk factors (Table 4).

Results

Visual attention

Adults

Results from the first three columns in Tables 2 and 4 indicate that participants dwelled on the brand/logo area of the packs (bottom 50%) for more time in the SGW text condition than for any other condition with FDA text (FDA text only, graphic FC, and graphic B&W). Respondents viewing graphic FC warnings spent more time looking at the warning (top 50%) than those viewing graphic B&W or SGW text-only. In addition, participants looked at the image AOI (text excluded) longer if it was in color than if it was in black and white.

Youth

The results from the first three columns in Tables 2 and 4 indicate that there were no differences by warning condition (excluding the brand-only control group) on visual attention to the brand/logo area of the packs (bottom 50%). Youth viewing graphic FC warnings spent more time looking at the warning (top 50%) than those viewing new FDA text-only. Youth also looked longer at the graphic part of the image (not the text) if it was in FC than if it was in B&W.

Negative affect

Adults

Respondents exposed to graphic warning labels (in FC or B&W) reported greater negative affect than those exposed to either text-only condition or the brand-only control (Tables 2 and 3). Respondents exposed to text-only labels (new FDA or SGW) also reported more negative affect than respondents exposed to the brand-only condition (Table 2).

Youth

Respondents exposed to any warning label (graphic or text-only) reported greater negative affect than those exposed to the brand-only control (Tables 2 and 5).

Health risk beliefs, intentions to quit and smoking susceptibility

There were no significant differences ($p < .05$) between any of the randomized conditions in levels of risk beliefs (old or new) quit intentions, or smoking susceptibility (Tables 2, 3 and 5).

Discussion

Summary of findings

This study compared how exposure to less extensive alternatives to the full-color graphic warnings proposed by the FDA

Table 3. Regression models predicting visual fixation, negative affect, risk beliefs, and intention to quit (adults).

	Fixation on Brand	Fixation on Warning	Fixation on Image	Negative Affect	Old Risk Beliefs	New Risk Beliefs	Intention to Quit
Condition (vs. GFC)							
Graphic B&W	1.15 (3.15)	−7.37 (3.60)*	−6.78 (2.26)**	−.17 (.17)	.29 (.17)	−.01 (.20)	−.17 (.51)
New FDA text only	2.81 (3.04)	−5.11 (3.48)	–	−.62 (.17)***	.02 (.17)	−.24 (.19)	−.01 (.48)
SGW text only	9.17 (3.07)**	−11.19 (3.50)**	–	−.81 (.17)***	.05 (.17)	−.29 (.19)	.38 (.47)
Brand only	39.39 (3.07)^	–	–	−1.14 (.17)***	−.08 (.17)	−.33 (.19)	.17 (.47)
Covariates							
Age	−.17 (.08)*	−.06 (.10)	−.08 (.09)	.01 (.00)	.00 (.00)	−.00 (.01)	.01 (.01)
Male (vs. female)	1.81 (2.12)	1.01 (2.74)	1.88 (2.49)	−.32 (.12)**	.07 (.12)	−.10 (.13)	.09 (.34)
Other gender (vs. female)	−3.03 (16.87)	−8.62 (19.30)	9.85 (12.22)	−1.66 (.93)	−3.59 (.93)***[a]	−1.90 (1.07)	−19.3 (4e^5)
Hispanic	.27 (3.42)	.43 (4.41)	−6.86 (4.62)	.46 (.19)*	−.34 (.19)	−.24 (.22)	−.07 (.51)
Black	−.71 (2.28)	3.06 (3.03)	−2.00 (2.68)	.37 (.13)**	−.19 (.13)	−.27 (.14)	.44 (.34)
Other, non-White race	1.61 (3.14)	9.45 (4.34)*	4.90 (3.64)	−.34 (.17)*	.15 (.17)	−.01 (.20)	.17 (.46)
$10K–$19K (vs. <$10K)	3.43 (2.40)	3.85 (3.16)	2.45 (2.78)	.06 (.13)	.04 (.13)	−.08 (.15)	.54 (.36)
$20K+ (vs. < $10K)	−.27 (2.80)	−2.81 (3.67)	1.43 (3.50)	−.02 (.15)	−.01 (.15)	.01 (.18)	−.14 (.44)
High school (vs. no HS)	.91 (2.13)	−1.16 (2.74)	.40 (2.38)	.04 (.12)	.03 (.12)	.00 (.14)	.37 (.34)
College (vs. no college)	1.78 (3.70)	−2.81 (4.77)	.39 (4.77)	.00 (.19)	−.01 (.20)	.24 (.23)	.49 (.48)
Nicotine dependence	−.13 (.44)	.16 (.56)	.08 (.49)	.00 (.02)	−.03 (.02)	−.03 (.03)	−.01 (.07)
Previous quit attempt	−1.41 (2.01)	.33 (2.58)	1.99 (2.36)	.19 (.11)	.02 (.11)	.12 (.13)	1.05 (.33)**
Emergency food	−.76 (2.54)	−4.89 (3.36)	2.81 (3.24)	−.05 (.14)	.09 (.14)	.16 (.16)	−.31 (.39)
WIC recipient	−2.67 (2.76)	4.28 (3.47)	.17 (2.91)	.12 (.15)	.10 (.15)	.19 (.17)	.53 (.40)
SNAP recipient	−2.06 (2.66)	−3.13 (3.35)	.87 (2.88)	.13 (.15)	.05 (.15)	.39 (.17)*	.12 (.42)
Colorblind	2.84 (3.16)	−3.59 (4.15)	1.45 (3.87)	.19 (.18)	.11 (.17)	.19 (.20)	−.26 (.52)
Constant	19.13 (5.90)***	50.24 (7.53)***	25.96 (6.80)***	2.67 (.32)***	3.56 (.32)***	3.75 (.37)***	−.91 (.91)
Adjusted R^2	.44	.04	−.01	.20	.04	.05	-
N	294	231	113	299	299	299	299

Note. Cells present unstandardized regression coefficients and standard errors. All models were ordinary least squares (OLS) regressions except for the model predicting susceptibility to smoke, which was a logistic regression model. ^ denotes that the control condition had no nonbrand area of interest (AOI) and was thus highly significant ($p < .001$). *$p \le .05$, **$p \le .01$, ***$p \le .001$. [a] This coefficient should be interpreted with caution, because very few respondents (n = 2) identified as other gender. GFC = Graphic full color; B&W = Black and white; FDA = Food and Drug Administration; SGW = Surgeon General's warning.

influences key variables proposed in the message impact framework. We observed some consistent patterns as well as differences across the two studies.

First, we find that graphic FC images hold visual attention. Both adult smokers and youth assigned to view FC graphic warnings spent more time looking at the graphic image (i.e., diseased lungs) than those who saw the same image in B&W. Adult smokers also looked at the overall warning for a longer period of time when assigned to graphic FC warnings compared to graphic B&W or SGW text-only versions, while youth looked at the graphic FC warnings longer than the FDA text-only warning. Differences in visual attention between graphic FC and other conditions, for both populations, were nonsignificant but similar in magnitude and always longest in the graphic FC conditions. We thus conclude that the overall pattern for both populations is consistent with the conclusion that graphic FC warnings garner the most attention, possibly owing to a combination of attracting viewers to the images and processing the new text.

Second, we find that warnings elicit negative affect. Among adult smokers, exposure to GWLs (in this case, both graphic FC and graphic B&W) produced greater negative affect than both text-only warning conditions and control. Whether these GWLs were in FC or B&W did not matter. Among middle-school youth, the pattern was quite different: exposure to any set of warning labels increased negative affect in participants compared to the control packs without warnings. Given that TCs argued that the U. S. government labels imposed emotionally charged message without any new health information, one key finding is that while warnings with images are highly associated with negative emotion for adults, the new labels do not necessarily generate any more emotion for youth than simply putting the SGWs warning on the front of the box.

Third, across both youth and adult smokers, those who viewed graphic FC warning labels did not report a significant increase in old or new risk beliefs, intentions to quit (among adult smokers), or susceptibility to smoke (among youth) compared to those assigned to other label conditions. All indices of risk beliefs were very high (suggesting the potential for ceiling effects), and we did not design our randomized experiments to have sufficient statistical power to detect effects on quit intentions or smoking susceptibility of the magnitude typically found in clinical trials or observational studies (e.g., Brewer et al., 2016; Noar et al., 2016b). The message impact framework (Noar et al., 2016a, 2016b) also suggests that these downstream effects are likely mediated by affective responses to warning labels. Thus, it is unreasonable to expect to observe direct effects on quit intentions or smoking susceptibility in response to a single session featuring 90 s of exposure. We did run a series of subsequent analyses in which we predicted (a) quit intentions as a function of all variables included in Table 3 (excluding the warning label conditions but adding negative affect to the model) and (b) smoking susceptibility as a function of all variables included in Table 4 (again excluding the warning label conditions but adding negative affect to the model). These analyses showed that the negative affect was a robust predictor of quit intentions among adult smokers (B = 0.30, odds ratio = 1.36, p = 0.04) and both new risk beliefs (standardized beta = 0.24, p < 0.001) and old risk beliefs (standardized beta = 0.23, p < 0.001) among youth. These results echo strong and consistent evidence from previous studies (e.g., Byrne et al., 2015; Brewer et al., 2016; Evans et al., 2015; Noar et al., 2016b) supporting the assertion that negative affect is likely to translate into favorable, downstream effects on quit intentions among smokers and health risk perceptions among (largely nonsmoking) youth.

Table 4. Regression models predicting visual fixation, negative affect, risk beliefs, and susceptibility to smoke (youth).

	Fixation on Brand	Fixation on Warning	Fixation on Image	Negative Affect	Old Risk Beliefs	New Risk Beliefs	Susceptible to Smoke
Condition (vs. GFC)							
Graphic B&W	−2.17 (2.04)	−4.23 (2.67)	−4.01 (1.93)*	.10 (.16)	.35 (.24)	.14 (.21)	−.09 (.40)
New FDA text only	1.25 (2.08)	−6.04 (2.73)*	–	.02 (.16)	.28 (.25)	.16 (.21)	.14 (.41)
SGW text only	.50 (2.02)	−5.07 (2.65)	–	.04 (.16)	.28 (.24)	−.23 (.20)	.13 (.41)
Brand only	36.02 (2.01)^	–	–	−.47 (.16)**	.06 (.24)	−.28 (.20)	.12 (.39)
Covariates							
Age	−.13 (.672)	.35 (.99)	−.11 (1.00)	−.06 (.05)	.12 (.08)	.16 (.07)*	−.16 (.13)
Male (vs. female)	−.85 (1.324)	−3.88 (1.95)*	1.32 (1.93)	−.09 (.10)	.23 (.16)	.13 (.13)	−.11 (.26)
Other gender (vs. female)	−2.90 (3.67)	5.16 (5.34)	2.79 (4.88)	−.14 (.29)	.39 (.45)	.51 (.38)	−2.28 (1.10)*ª
Hispanic	−3.57 (2.75)	6.63 (4.09)	−3.30 (4.47)	−.42 (.22)*	.27 (.33)	.14 (.28)	.36 (.54)
Black	−3.28 (1.89)	−.71 (2.84)	−.05 (2.94)	−.05 (.14)	.07 (.22)	.15 (.18)	.42 (.35)
Other, non-White race	−2.12 (1.74)	−2.27 (2.56)	.08 (2.59)	.05 (.13)	.10 (.21)	.16 (.17)	.23 (.34)
Previous smoking	−3.19 (2.39)	−.48 (3.30)	.38 (3.21)	−.09 (.19)	.50 (.29)	.35 (.25)	2.02 (.60)***
Smoking environment	−.16 (1.32)	.29 (1.94)	−1.89 (2.02)	.06 (.10)	−.23 (.16)	−.26 (.13)*	.85 (.26)***
Sensation seeking	.56 (.86)	.50 (1.27)	−.33 (1.28)	−.12 (.07)	−.05 (.10)	.00 (.09)	.89 (.18)***
Colorblind	1.24 (2.52)	4.87 (3.58)	1.95 (3.35)	−.12 (.19)	.35 (.30)	.35 (.25)	−.20 (.50)
Constant	19.48 (8.39)*	38.39(12.37)***	27.09 (12.66)*	3.33 (.64)***	1.43 (.97)	1.85 (.81)*	−.85 (1.59)
Adjusted R^2	.64	.01	−.02	.05	.01	.04	–
N	303	240	123	324	329	328	329

Note. Cells present unstandardized regression coefficients and standard errors. All models were ordinary least squares (OLS) regressions except for the model predicting susceptibility to smoke, which was a logistic regression model. ^ denotes that the control condition had no nonbrand area of interest (AOI) and was thus highly significant (p < .001), *p ≤ .05, **p ≤ .01, ***p ≤ .001. ª This coefficient should be interpreted with caution, because very few respondents (n = 10) identified as other gender. GFC = Graphic full color; B&W = Black and white; FDA = Food and Drug Administration; SGW = Surgeon General's warning.

Study implications

We offer mixed findings related to the claim that a less extensive regulation could satisfy the government's compelling public health interest to reduce cigarette smoking rates. On the one hand, graphic FC warning labels do generate greater visual attention compared to other variations across the board, consistent with the argument that graphic FC warnings are an optimal configuration. This outcome is the most proximal DV from the message impact framework tested in the current study and thus might be expected to offer the clearest pattern of effects from a single, short-term warning label exposure. On the other hand, graphic FC labels produced levels of negative affect equivalent to graphic B&W labels among adults, while both graphic and text-only labels performed similarly in generating negative affect among (largely) nonsmoking youth. We thus cannot draw definitive conclusions about the degree to which graphic FC labels are necessary to achieve downstream public health goals. That said, we conducted these studies among two populations that one would expect to be very difficult to influence—adult smokers from highly disadvantaged socioeconomic backgrounds (who experience immense barriers to quitting) and middle-school youth at high risk of future smoking uptake (owing to high rates of living with smokers and similarly economically disadvantaged backgrounds). We thus conclude that the current study does not rule out the possibility that graphic FC warnings offer incremental benefits over less extensive alternatives, as is evidenced by a large international research base demonstrating that pictorial warnings result in intended effects over time. It is therefore plausible that the incremental benefits observed here may scale up toward a larger impact at the population level.

Limitations and future research

As noted above, it is important to consider that the exposure in this study takes place over 90 s. If FC warning labels are implemented in the United States, the levels and durations of exposure will be considerably longer and more frequent. We cannot speak the

effects of repeated exposure to attention-grabbing, graphic FC warning labels. These studies reported here also rely on self-reported measures to gauge both emotional reactions and health risk beliefs, suggesting that future studies examine the effects of these label manipulations on behavioral outcomes measured over a longer period of time. In addition, we used brand imagery from three specific TCs in an effort to assess visual attention to warning labels versus branded content. However, our study did not include a variety of other brands that smokers may use regularly.

We did not examine the aspects of all of the legal challenges to the Tobacco Control Act. Particularly, the FDA has the authority to place GWLs on ads for cigarettes. Cigarette ads often market their product by depicting attractive, social youth engaged in cool activities. On the one hand, these visual depictions of benefits of smoking might distract from the warnings, but one could easily argue the opposite might be true. If warnings on ads distract from elements compelling youth to take up smoking, the warnings could provide a public health benefit.

Conclusion

This study offers new evidence on the relative importance of graphic full color, graphic black and white, and text-only cigarette warning labels in shaping visual attention, negative affect, and health risk beliefs. The results reveal that graphic full-color images held visual attention for a longer duration than less restrictive alternatives. Graphic images (whether in full color or in black and white) also produced higher levels of negative affect among adult smokers, but graphic images did not outperform text-only warnings of similar magnitude among at-risk but largely nonsmoking, middle-school youth. Findings raise important new questions about the optimal design of GWLs to increase cessation among adult smokers and increase understanding of the health risks of smoking among youth from socioecomically disadvantaged backgrounds.

Disclosure of potential conflicts of interest

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Responses of young adults to graphic warning labels for cigarette packages

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ABSTRACT

Background In 2010, the US Food and Drug Administration (FDA) proposed a series of 36 graphic warning labels for cigarette packages. We sought to evaluate the effects of the labels on fear-related emotions about health consequences of smoking and smoking motivations of young adults.

Methods We conducted an experimental study in 2010–2011 with 325 smokers and non-smokers ages 18–30 years whom we recruited through community distribution lists in North Carolina and through a national survey company. Each participant viewed 27 labels (18 of the proposed labels with graphic images and text warnings and 9 with text-only warnings) in a random order, evaluating each label on understandability and its effects on fear-related reactions and discouragement from wanting to smoke.

Results Respondents found most of the proposed labels easy to understand. Of the 36 labels, 64% induced greater fear-related reactions and 58% discouraged respondents from wanting to smoke more than the corresponding text-only labels did. Labels with the greatest effects had photographs (as compared with drawings or other art graphics) or depicted diseased body parts or suffering or dead people. In almost every comparison, smokers reported lower fear-related reactions and feeling less discouraged from wanting to smoke relative to non-smokers.

Conclusions Most of the proposed labels enhanced fear-related reactions about health consequences of smoking and reduced motivations to smoke relative to text-only labels, although some had larger effects than others. All but one of the nine warning labels recently adopted by the FDA enhanced fear-related reactions and reduced smoking motivations.

INTRODUCTION

Smoking is the leading cause of death in the USA[1] and the rest of the developed world.[2] Tobacco control efforts focus on discouraging smoking initiation by non-smokers and encouraging smokers to stop. In many countries, these efforts include policies requiring warning messages on tobacco products. The WHO's Framework Convention on Tobacco Control (FCTC) calls for the implementation of large warning labels on tobacco products, preferably with graphic images that communicate the potential consequences of smoking.[3 4] To date, more than 45 countries require warning labels with graphic images.[4]

Message processing and persuasion theories suggest that graphic warnings can discourage smoking when viewers understand the messages they are conveying and when the warnings arouse fear and worry about the consequences.[5–8]

Cognition and neuroscience research demonstrates that imagery-based information can elicit faster processing, stronger emotional responses, stronger attitude development and easier recall than text-based information.[9 10] Thus, graphic warning labels may have a greater impact on smoking motivations than do text-based labels that convey the same messages, particularly if they provoke feelings of worry and fear about harm.[5 7 11] Consistent with this theoretical and empirical base, a growing body of research supports the use of graphic warning labels over text-only labels for cigarettes.[12] Compared with text-only warning labels, graphic warning labels can evoke stronger emotional responses and increase motivations to not smoke or attempt quitting.[4 13–20]

The 2009 Family Smoking Prevention and Tobacco Control Act calls for the implementation of graphic warning labels on cigarette packaging and advertisements in the USA. In November 2010, the Food and Drug Administration (FDA) made available to the public a set of 36 proposed warning labels from which they planned to select 9 labels for use. It is important to understand the potential impact of these labels, especially among young adults as they may be less aware or concerned about the health consequences of smoking relative to older adults.[21] Moreover, non-smoking young adults represent a vulnerable group for smoking initiation because many smokers begin smoking regularly when they are in this age range.[22–26]

The graphic warning labels could have a greater impact for non-smokers than for smokers because non-smokers may have less personal experience with smoking, and contemplating the potential harms of smoking and their smoking choices are not constrained by addiction. Non-smokers are likely to view the FDA warnings because Tobacco Control Act requires them to be displayed not just on cigarette packs but on all cigarette advertising, including posters and magazine advertisements. These tobacco promotional materials are not benign; for example, exposure to 'point of sale' advertising (eg, posters at convenience stores) is associated with increased smoking susceptibility and initiation among non-smokers.[27]

We conducted an experimental study with young adults (18–30 years old) in the USA to examine their responses to the 36 proposed warning labels, with particular attention to the nine labels ultimately selected by the FDA. We evaluated which labels, relative to text-only labels, are more easily understood and produce greater fear-related reactions and discouragement from wanting to smoke. We also examined whether non-smokers have

stronger reactions of fear-related emotions and feeling discouraged from wanting to smoke than do smokers. Finally, we explored which types of images in graphic labels are most likely to reduce smoking motivations. This analysis follows preliminary research guided by theory on mental models of health risks[5] [28] that evaluated how imagery elements influenced responses by community members to graphic warning labels proposed for use in the European Union.[29] Consistent with the theory that individuals are predisposed to encode and process information about the symptoms and identity (including prototypical individuals affected by the threat) labels depicting diseased body parts (eg, neck tumors), dead or suffering people, and children or babies were more likely than other labels to be viewed as effective in discouraging people from smoking. In contrast, use of art graphics (eg, drawings rather than photographs) and metaphors (eg, a wrinkled apple to depict ageing skin) decreased the likelihood of a label being perceived as effective, potentially due to the lower realism; medical equipment, an image used to depict severity of health consequences, had little impact on perceived effectiveness. We coded the FDA's proposed labels for these image categories and an additional category of unpleasant smoking experiences, which emerged as a common theme and provided smoking cues that could potentially trigger urges to smoke.[30]

METHODS
Participants
The University of North Carolina Institutional Review Board approved the study. Eligible adults, who were 18–30 years old and residing in the USA, participated in the study from December 2010 to January 2011 between the FDA's release of the warning labels (November 2010) and their announcement of the final selection of labels (June 2011). The study included a convenience sample of adults who responded to email announcements sent through community distribution lists managed by the University of North Carolina and to posts on a national website service for recruiting survey respondents (Amazon Mechanical Turk or MTurk). Participants received a $5 gift certificate or payment through MTurk.

Design
The study utilised a split-plot design with smoker status (smoker or non-smoker) as the between-subjects variable and warning label (graphic vs text-only comparison) as the within-subjects variable. Each participant viewed 18 of the 36 proposed labels, which the FDA grouped into nine warning categories,[31] and nine text-only labels, each with the warning statement for one of the nine categories.

Materials and procedure
Because of the large number of labels, we developed two versions of an online questionnaire (Versions A and B), each of which contained 18 of the 36 proposed labels and the nine text-only labels. The labels are presented in the online supplementary materials. The text-only labels were designed to control for text message, label size and the use of red, black and white colours in the backgrounds and text of the proposed graphics labels. These text-only labels presented the warning statements in white and red text against a black background. Each label appeared on the face of an image of a cigarette pack and comprised top 50% of the front panel; the word 'Brand' appeared below the label.

After completing the measures of smoking behaviour and demographic characteristics, participants randomly received

questionnaire Version A or Version B and viewed 27 labels in random order. They rated each label on understandability, how much it aroused fear-related reactions and how much it discouraged them from wanting to smoke. On average, participants completed the survey in approximately 16 min.

Measures
Smoking behaviour
Smoking status was assessed with two items, 'How often do you smoke now?' (response options were: never, I am not a smoker; less than once a month; at least once a month; at least once a week; and at least once a day) and 'Have you smoked cigarettes 100 or more times in your life?' (response options were: yes and no). Using widely accepted definitions of smoking status,[32] we categorised participants as smokers if they reported non-daily or daily smoking (less than once a month through at least once a day). We categorised participants as former smokers if they were non-smokers who had smoked cigarettes 100 times or more.

Understandability
Participants responded to the question 'How would you describe the message conveyed by this label?' by rating their endorsement of two items: 'The message is easy to understand' and 'The message is confusing'. Each had response options of not at all (coded as 1), slightly (2), somewhat (3) or a great deal (4). We reverse-scored the latter item before averaging the ratings. Across the 36 graphic labels, the average correlation of the two items was moderate; mean $r=0.65$.

Fear-related reactions
A short measure, adapted from a measure developed by Brown and Smith[33] for a young adult sample, included two items: 'How much does this image make you feel worried?' and 'How much does this image make you feel scared?' Response scales ranged from not at all (1) to extremely (7). We averaged the two ratings (mean $r=0.94$ across the 36 labels) to generate scores. These items are also similar to those used to measure emotional reactions to warning labels in samples that included young adults.[34–36]

Discouraged from smoking
The item 'How much does this label discourage you from wanting to smoke cigarettes?' had response options ranging from not at all (1) to very much (5).

Image themes
To explore the potential impact of specific images, we coded the labels according to seven *image themes* derived from prior research on graphic warning labels.[16] These themes were: (1) diseased body parts; (2) suffering or dead people; (3) children or babies; (4) art graphics (image with graphic design elements or drawings rather than a photograph); (5) metaphors (symbolic representations; eg, a puppet on strings to convey addiction); (6) medical equipment (eg, an oxygen mask); and (7) unpleasant smoking experiences (people smoking in unpleasant situations or eliciting aversive reactions from others). Some labels fit into multiple image theme categories and were coded accordingly. Two raters independently coded the labels for image themes. Inter-rater reliability was 100%.

Analyses
We conducted preliminary analyses (correlations and t tests) to test associations of age and sampling groups (those recruited through North Carolina distribution lists vs MTurk) with the

dependent measures of understandability, fear-related reactions and discouragement from wanting to smoke. We also conducted preliminary analyses of variance (ANOVA) to test for differences between current smokers, former smokers and non-smokers on these dependent measures.

We evaluated the understandability of the proposed graphic warning labels by examining the sample means of the understandability scores. We used a series of 2×2 split-plot ANOVAs to test the effects of labels (each proposed graphic warning label vs its corresponding text-only label; a within-subjects variable) and smoker status (smoker vs non-smoker; a between-subjects variable) on fear-related reactions scores. We repeated these ANOVAs for ratings of discouragement from wanting to smoke. Preliminary split-plot ANOVA for fear-related reactions and discouragement from wanting to smoke included demographic variables as covariates where they were statistically significant predictors to determine whether they should be included in the final analyses.

We calculated the average effect sizes for the image themes' effects on ratings of feeling discouraged from smoking (using partial eta squared or η_p^2, a measure of the variance in an outcome explained by a predictor[37]). These seven effect sizes were compared to identify which image themes elicited the largest effects on smoking motivations. We conducted the analyses using SPSS V.19 in 2012. Analyses were two-tailed with a critical $p<0.01$.

RESULTS
Sample characteristics
The sample included 325 participants from 43 states across the nation; 111 (34.3%) were recruited through community distribution lists and 214 (65.7%) were recruited through MTurk.

Most participants were ages 18–21 (39.1%) or 22–25 (48.3%). Preliminary ANOVAs revealed that age and sampling groups were not related to the dependent variables of understandability, fear-related reactions and discouragement from wanting to smoke. About 17 participants (5.2%) were former smokers. Preliminary ANOVAs indicated that former smokers did not differ from non-smokers on any of the dependent variables, and the patterns of differences between former and current smokers were similar to those between non-smokers and current smokers. As the small number of former smokers does not provide sufficient power to draw conclusions about group differences, we dropped former smokers from the remaining analyses. Table 1 presents the sociodemographic characteristics of non-smokers and smokers. Relative to non-smokers, smokers tended to be older by about 1 year; a higher proportion were men, employed in full-time or part-time work and married; and a lower proportion were students. Preliminary split-plot ANCOVAs included these variables as covariates where they were statistically significant predictors. Their inclusion did not alter any of the patterns of Label and Smoker Status effects, and so they were omitted from the final analyses.

Understandability
Participants generally found the proposed graphic warning labels easy to understand (see table 2). Ratings of understandability were generally high, with mean ratings ranging from 3.50 to 4.00 for 28 of the 36 labels. Labels with mean ratings lower than 3.50 included three of the four labels from the 'Cigarettes are Addictive' warning category (Cigarette Injection, Red Puppet and Woman in Rain), one label from the 'Cigarettes

Table 1	Sociodemographic characteristics of the sample (N=308)		
Characteristic	Non-smokers, n (%) (n=195; 63.3%)	Smokers, n (%) (n=113; 36.7%)	Smoker status effect
Age, mean (SD)	22.19 (3.18)	23.44 (3.23)	$F_{(1,307)}=10.76^{**}$
Gender			$\chi^2=6.23^*$
Female	144 (73.8)	68 (60.2)	
Male	51 (26.2)	45 (39.8)	
Race/ethnicity			$\chi^2=12.11^{**}$
Non-hispanic white	138 (70.4)	100 (87.0)	
Non-hispanic black	25 (12.8)	4 (3.5)	
Asian	30 (15.3)	6 (5.3)	
Hispanic	12 (6.1)	5 (4.4)	
Other	4 (2.5)	7 (6.2)	
Education level			$\chi^2=7.57$
Some high school	0 (0.0)	1 (0.9)	
High school graduate or equivalent	32 (16.4)	25 (22.0)	
Technical or trade school	2 (1.0)	4 (2.5)	
Some college	83 (42.6)	49 (43.4)	
College graduate	78 (40.0)	34 (30.0)	
Employment status			$\chi^2=8.62^*$
Full time	39 (20.0)	39 (34.5)	
Part time	70 (35.9)	36 (31.9)	
No	86 (63.5)	38 (33.6)	
Student status			$\chi^2=13.58^{**}$
Full time or part time	137 (70.2)	55 (50.4)	
Not a student	58 (29.7)	57 (49.6)	
Marital status			$\chi^2=11.34^{**}$
Single–never married	153 (78.5)	73 (65.2)	
Married or living with partner	42 (21.5	35 (31.2)	
Separated or divorced	0 (0.0)	4 (3.6)	

*p<0.05, **p<0.01.

Table 2 Graphic warning labels included in questionnaire versions A and B and their understandability ratings

Warning category	Questionnaire version A		Questionnaire version B	
	Label	Understandability, mean (SD)	Label	Understandability, mean (SD)
Cigarettes are Addictive	**Hole in Throat**	3.58 (0.72)	Red Puppet	3.41 (0.78)
	Cigarette Injection	3.32 (0.88)	Woman in Rain	3.15 (0.94)
Tobacco Smoke Can Harm Your Children	**Smoke Approaching Baby**	3.77 (0.56)	Smoke at Toddler	3.74 (0.50)
	Smoke at Baby	3.80 (0.49)	Girl Crying	3.59 (0.69)
	Girl with Oxygen Mask	3.59 (0.68)	Child Lettering	3.66 (0.50)
Cigarettes Cause Fatal Lung Disease	Toe Tag	3.74 (0.56)	**Healthy/Diseased Lungs**	3.68 (0.57)
	Lungs Full of Cigarettes	3.60 (0.70)	Doctor with X-Ray	3.60 (0.64)
Cigarettes Cause Cancer	Deathly Ill Woman	3.82 (0.45)	Red Cigarette Burning	3.67 (0.55)
	White Cigarette Burning	3.70 (0.59)	**Cancerous Lesion on Lip**	3.73 (0.59)
Cigarettes Cause Strokes And Heart Disease	Hand With Oxygen Mask	3.52 (0.68)	Man Pain-Hand on Chest	3.68 (0.55)
	Red Lightning with Heart	3.41 (0.78)	**Oxygen Mask Man's Face**	3.73 (0.52)
Smoking During Pregnancy Can Harm Your Baby	Pacifier and Ashtray	3.74 (0.54)	**Baby in Incubator**	3.72 (0.52)
Smoking Can Kill You	**Man with Chest Staples**	3.68 (0.62)	Man in Casket	3.74 (0.53)
	Red Coffin with Body in Black	3.71 (0.66)	Cigarettes=RIP	3.66 (0.59)
Tobacco Smoke Causes Fatal Lung Disease in Non-smokers	**Woman Crying**	3.36 (0.80)	Woman Smoke at Man	3.55 (0.69)
	Graveyard	3.58 (0.68)	Man Hands Up and Smoke	3.53 (0.71)
	Man Smoke at Woman	3.65 (0.67)		
Quitting Smoking Now Greatly Reduces Serious Risk To Your Health	Cigarettes in Toilet Bowl	3.24 (0.90)	Woman Blowing Bubble	2.82 (0.98)
			Man in 'I Quit' T-Shirt	3.43 (0.73)

Warning categories are those defined by the Food and Drug Administration (FDA). Label names are those used by Nonnemaker et al.[34] Understandability scores range from 1 (not at all) to 4 (a great deal). The labels selected by the FDA in June 2011 appear in bold.

Cause Strokes and Heart Disease' category (Red Lightning with Heart), one label from the 'Smoking Causes Fatal Lung Disease in Non-smokers' category (Woman Crying) and all three labels in the 'Quitting Smoking Now Greatly Reduces Serious Risk to Your Health' category (Cigarettes in Toilet Bowl, Woman Blowing Bubble, Man in 'I Quit' T-Shirt). The nine labels ultimately selected by the FDA (presented in bold) had high understandability scores with the exceptions of Woman Crying and Man in 'I Quit' T-Shirt, although the latter had the highest rating of the labels in its warning category. Across the 36 proposed labels, understandability tended to be modestly related to higher fear-related reactions (average r=0.24; range=0.09–0.41; at r=0.24, p<0.01) and greater discouragement from wanting to smoke (average r=0.27; range=0.19–0.43; at r=0.27, p<0.01).

Fear-related reactions

Table 3 presents the fear-related reactions means (SDs) and image themes for the graphic warning labels, with the nine labels ultimately selected by the FDA in bold. Overall, 25 of the 36 graphic warning labels induced greater fear-related reactions compared with their corresponding text-only labels. Many of these labels had large effects. Figure 1 depicts the eight labels with the greatest impact on fear-related reactions based on the ranking of effect sizes. Notably, these labels consisted primarily of images depicting diseased body parts (four labels) and suffering or dead people (four labels).

Eleven labels induced comparable fear-related reactions relative to the text-only labels. These labels consisted primarily of images with art graphics (five labels), metaphors (three labels), unpleasant smoking experiences (three labels) and medical equipment (one label). Two graphic labels induced lower fear-related reactions than their text-only versions; both focused on the reassuring message that 'quitting smoking now reduces serious risk to your health' and used metaphors: Man in 'I Quit' T-Shirt and Woman Blowing Bubble.

The labels selected by the FDA induced more fear-related reactions than their corresponding text-only labels did, with the exception of Man in 'I Quit' T-Shirt. Five of these labels had the largest effects on fear-related reactions within their respective warning categories.

For almost every label, non-smokers reported greater fear-related reactions than smokers did. The only exceptions were that non-smokers and smokers gave comparably low ratings for the Man in 'I Quit' T-Shirt and Woman Blowing Bubble labels.

Label × Smoking Status interaction effects emerged as statistically significant for only four labels. For two labels, the graphic contents increased fear-related reactions for non-smokers (p's<0.01) but not for smokers (p's>.20). These labels were: Smoke Approaching Baby, $F(1, 144)=9.45$, $p<0.01$; $\eta_p^2=0.06$; and Pacifier in Ashtray, $F(1, 144)=8.03$, $p<0.01$, $\eta_p^2=0.06$. In contrast, two labels (relative to the text-only label) induced greater increases in fear-related reactions for smokers than they did for non-smokers: Red Cigarette Burning, $F(1, 146)=9.39$, $p<0.01$, $\eta_p^2=0.06$; and Cancerous Lesion on Lip, $F(1, 144)=7.26$, $p<0.01$, $\eta_p^2=0.06$. Whereas smokers reported lower fear-related reactions than non-smokers did to the text-only label (M=2.95 vs M=4.14, respectively; p<0.001); smokers and non-smokers reported comparably high fear-related reactions to these graphic labels: for Red Cigarette Burning, M=3.63 vs M=4.25, p>0.10; and for Cancerous Lesion on Lip, M=4.51 vs M=4.91, p>0.25. Across the 36 labels, fear-related reactions were associated with greater discouragement from wanting to smoke (average r=0.69, range=0.65–0.78; at r=0.69, p<0.001).

Discouragement from wanting to smoke

Overall, 22 of the 36 graphic warning labels discouraged participants from wanting to smoke more than corresponding text-only labels did (see table 4). Figure 1 depicts the mean ratings for the eight labels that had the greatest impact based on

Table 3 Fear-related reactions induced by graphic versus text warning labels for non-smokers (n=195) and smokers (n=113)

Label	Image themes	Graphic label M (SD)	Text label M (SD)	Label effect F	η_p^2	Non-smokers M (SD)	Smokers M (SD)	Smoker status effect F	η_p^2
Cigarettes are Addictive									
Hole in Throat	D	4.50 (2.18)	2.79 (1.82)	98.56***	0.42	4.15 (1.91)	2.76 (1.85)	23.81***	0.15
Cigarette Injection	M, A	3.54 (2.14)	2.79 (1.82)	20.85***	0.13	3.72 (1.98)	2.25 (1.59)	26.24***	0.16
Red Puppet	M, A	3.03 (1.69)	2.79 (1.75)	3.16	0.02	3.30 (1.74)	2.29 (1.48)	16.17***	0.11
Woman in Rain	U	2.74 (1.69)	2.79 (1.75)	0.17	0.00	3.11 (1.75)	2.23 (1.53)	11.75***	0.08
Tobacco Smoke Can Harm Your Children									
Smoke Approaching Baby	C	4.49 (2.12)	3.79 (2.16)	20.35***	0.13	4.65 (1.95)	3.28 (1.95)	15.72***	0.10
Smoke at Baby	C, A, U	4.35 (2.14)	3.79 (2.16)	15.25***	0.10	4.53 (2.02)	3.31 (2.02)	11.77***	0.08
Girl with Oxygen Mask	C, S, E	4.33 (2.14)	3.79 (2.16)	14.22***	0.09	4.50 (2.03)	3.32 (2.03)	12.24***	0.08
Smoke at Toddler	C	4.34 (2.00)	3.63 (2.00)	30.57***	0.18	4.38 (2.05)	3.36 (2.05)	10.88***	0.07
Girl Crying	C, S	4.17 (2.18)	3.63 (2.00)	12.89***	0.07	4.33 (2.00)	3.27 (2.00)	11.95***	0.08
Child Lettering	A	3.55 (2.07)	3.63 (2.00)	1.60	0.01	4.03 (2.02)	2.91 (2.02)	12.22***	0.08
Cigarettes Cause Fatal Lung Disease									
Healthy/Diseased Lungs	D	4.71 (1.98)	3.71 (2.01)	59.77***	0.30	4.50 (1.96)	3.78 (1.96)	5.46*	0.04
Toe Tag	S	4.38 (2.17)	3.63 (1.99)	43.02**	0.24	4.49 (2.01)	3.16 (2.01)	16.56***	0.11
Lungs Full of Cigarettes	M	4.05 (2.09)	3.63 (1.99)	10.37**	0.07	4.37 (1.99)	2.91 (1.99)	22.09***	0.14
Doctor with X-Ray	E	3.75 (2.01)	3.71 (2.01)	0.21	0.00	4.12 (1.99)	3.15 (1.99)	10.16**	0.07
Cigarettes Cause Cancer									
Deathly Ill Woman	S	5.06 (2.02)	3.83 (2.14)	66.01***	0.32	4.92 (1.93)	3.63 (1.93)	16.45***	0.11
Cancerous Lesion on Lip	D	4.75 (1.94)	3.66 (1.96)	60.55***	0.30	4.52 (1.95)	3.73 (1.95)	7.63**	0.05
Red Cigarette Burning	A	4.00 (2.05)	3.66 (1.96)	9.39**	0.06	4.19 (2.00)	3.29 (2.00)	8.56**	0.06
White Cigarette Burning	A	3.93 (2.15)	3.83 (2.14)	0.59	0.00	4.37 (2.05)	3.06 (2.05)	14.07***	0.09
Cigarettes Cause Stroke and Heart Disease									
Oxygen Mask on Man's Face	S, E	4.44 (2.09)	3.64 (1.95)	28.17***	0.17	4.49 (1.94)	3.40 (1.97)	12.77**	0.08
Hand with Oxygen Mask	E	4.01 (2.07)	3.64 (2.06)	7.08**	0.05	4.30 (1.97)	3.05 (2.00)	14.82***	0.10
Man in Pain-Hand on Chest	S	3.94 (1.97)	3.64 (1.95)	7.12**	0.05	4.20 (1.94)	3.21 (1.87)	11.44***	0.08
Red Lightening with Heart	A	3.72 (2.13)	3.64 (2.06)	0.04	0.00	4.19 (2.03)	2.85 (1.96)	15.52***	0.10
Smoking During Pregnancy Can Harm Your Baby									
Baby in Incubator	C,A,S,E	4.32 (2.26)	3.81 (2.16)	14.17***	0.09	4.47 (2.10)	3.50 (2.24)	8.39**	0.06
Pacifier in Ashtray	M	4.19 (2.20)	4.01 (2.16)	0.40	0.00	4.65 (1.99)	3.17 (2.17)	18.10***	0.12
Smoking Can Kill You									
Man with Chest Staples	S,D	4.41 (1.99)	3.72 (2.10)	26.41***	0.16	4.61 (2.04)	3.16 (1.97)	18.52***	0.12
Red Coffin with Body	A	4.07 (2.27)	3.72 (2.10)	5.25*	0.04	4.47 (2.11)	2.92 (1.97)	20.73***	0.13
Man in Casket	S	3.95 (2.19)	3.61 (2.03)	6.62*	0.05	4.30 (2.09)	3.08 (1.98)	14.68***	0.10
Cigarettes=RIP	A	3.57 (2.07)	3.61 (2.03)	0.73	0.00	4.05 (2.04)	2.93 (1.92)	11.71***	0.08
Tobacco Smoke Causes Fatal Lung Disease in Non-smokers									
Graveyard	M	4.32 (2.17)	3.82 (2.18)	13.63***	0.09	4.78 (1.96)	2.91 (2.02)	32.43***	0.19
Man Smoke at Woman	U	4.26 (2.18)	3.82 (2.18)	11.16***	0.07	4.69 (1.99)	2.93 (2.06)	27.89***	0.17
Woman Crying	S	4.11 (2.09)	3.82 (2.18)	5.03*	0.03	4.66 (1.94)	2.82 (1.98)	31.19***	0.18
Woman Smoke at Man	U	3.96 (2.10)	3.85 (2.04)	0.41	0.00	4.60 (1.88)	2.92 (1.93)	33.67***	0.20
Man Hands Up And Smoke	U	3.94 (2.20)	3.85 (2.04)	0.22	0.00	4.62 (1.94)	2.76 (1.86)	39.55***	0.22
Quitting Now Greatly Reduces Serious Risk to Your Health									
Cigarettes in Toilet Bowl	M	2.56 (1.76)	2.71 (1.76)	2.75	0.02	3.06 (1.80)	2.00 (1.53)	13.58***	0.09
Man in 'I Quit' T-Shirt	M	2.17 (1.50)	2.56 (1.74)	15.19***	0.10	2.51 (1.70)	2.15 (1.48)	2.04	0.01
Woman Blowing Bubble	M	1.97 (1.34)	2.56 (1.74)	25.07***	0.15	2.36 (1.56)	2.12 (1.51)	1.15	0.01

Fear-related reactions scores ranged from 1 (not at all) to 7 (extremely). Image themes: A, art-graphics; C, child/baby; D, diseased body part; E, medical equipment; M, metaphor; S, suffering or dead person; U, unpleasant smoking experience. η_p^2=proportion of variance explained. The labels selected by the Food and Drug Administration in June 2011 appear in bold.
*p<0.05, **p<0.01, ***p<0.001.

the ranking of effect sizes. Notably, these were the same eight labels that had the greatest impact on fear-related reactions.

Except for the Red Puppet label, all of the graphic labels that failed to enhance fear-related reactions relative to their text-only versions also failed to discourage respondents from smoking more than the text-only labels. Girl Crying, Hand with Oxygen Mask and Red Coffin also failed to discourage wanting to smoke

more than the text-only versions did. One graphic label was less discouraging than its text-only version: Man in 'I Quit' T-Shirt.

Once again, the ineffective labels had images consisting primarily of art graphics (five labels), metaphors (four labels), unpleasant smoking experiences (three labels) and medical equipment (two labels), although one label depicted a suffering person and a child.

Figure 1 The eight graphic warning labels with the greatest impact on: (A) fear of harms and (B) feeling discouraged from wanting to smoke.

(a) Fear-Related Reactions

(b) Feeling Discouraged from Wanting to Smoke
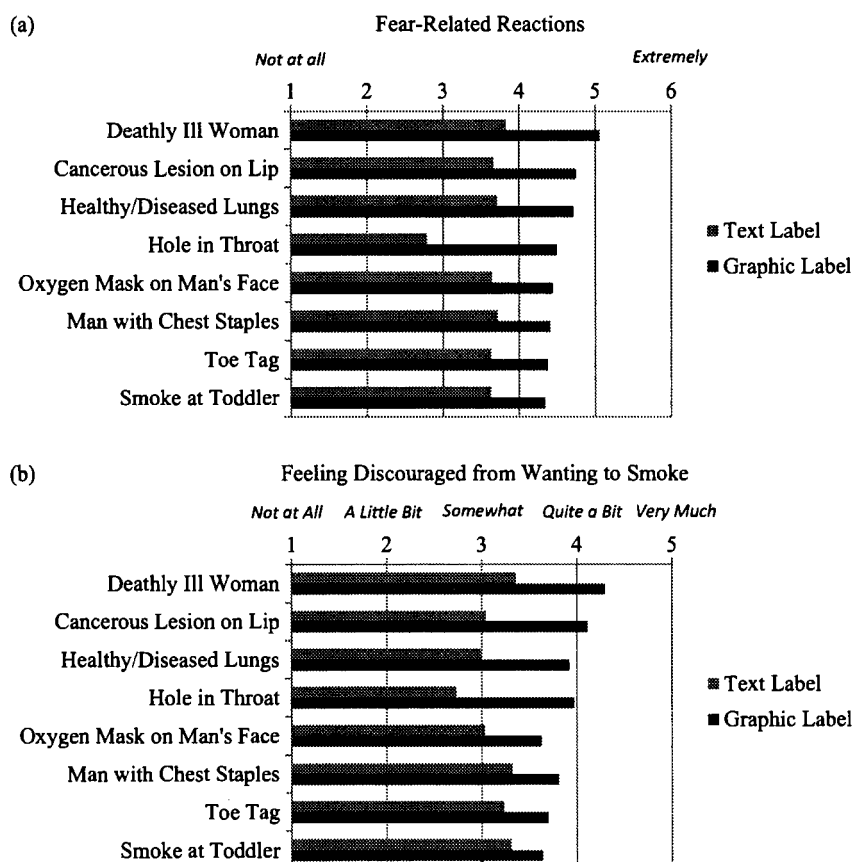
With the exception of Man in 'I Quit' T-Shirt, the labels that the FDA selected were more effective than the text-only labels in discouraging respondents from smoking. Five of these labels had the largest effects of those within their respective warning categories.

Analyses revealed substantial differences between non-smokers and smokers in their reports of feeling discouraged from smoking in response to the labels. Non-smokers reported relatively greater discouragement in response to all labels. None of the Label×Smoking Status interaction effects reached statistical significance.

Evaluations of the average effect sizes for labels within image theme categories revealed that the image theme that most discouraged smoking was diseased body parts (average $\eta_p^2=0.36$), followed by suffering or dead people (average $\eta_p^2=0.14$), children or babies (average $\eta_p^2=0.11$) and medical equipment (average $\eta_p^2=0.08$). Image themes with the smallest effect sizes were unpleasant smoking experiences (average $\eta_p^2=0.05$), art graphics (average $\eta_p^2=0.05$) and metaphors (average $\eta_p^2=0.04$).

DISCUSSION

Three key findings emerged from this study of the effects of the proposed graphic warning labels. First, the 36 proposed labels were easily understood, and many had greater effects than text-only labels on fear-related reactions and smoking motivations, including all but one of the nine labels that the FDA finally selected. Overall, 69% of them induced relatively greater fear-related reactions about the health consequences of smoking and 61% induced relatively greater discouragement from wanting to smoke. Second, the graphic warning labels compared with text-only labels induced greater fear-related reactions and

discouragement for both young adult smokers and non-smokers, but the effects were generally stronger for non-smokers. Third, labels with the greatest effects on discouragement from wanting to smoke generally included photographs of diseased body parts, suffering or dead people or children or babies, whereas labels with minimal effects generally included images consisting of art graphics, metaphors or depictions of unpleasant smoking experiences. These latter findings converge with evidence that labels with graphic depictions of disease have stronger effects on emotional reactions and smoking motivations than do images of human suffering or symbolic images.[16 34]

These results complement findings from two recent evaluations of the 36 proposed warning labels, indicating that many labels elicited stronger emotions or were perceived as more effective relative to text-only labels.[16 34] Similar to Nonnemaker and colleagues,[34] we also found no evidence that the graphic labels in the warning category, 'Quitting smoking now greatly reduces serious risk to your health,' affects emotional reactions and smoking motivations, and we found that the Woman Blowing Bubble image decreases motivations to not smoke. Hammond and colleagues[16] also identified elements associated with greater perceived effectiveness, including graphic images of disease or suffering as well as real people (vs comic book figures), a quitline number (vs no number), full colour (vs black and white) and personal information (eg, the sufferer's name and narrative).

The present study differs from the prior studies in several ways. First, the prior studies included smokers (all ages), and either non-smokers ages 16–18 or susceptible non-smokers ages 13–17. In contrast, this study included the vulnerable and large group of young adult non-smokers. Our findings add new

Table 4 Feeling discouraged from wanting to smoke in response to graphic versus text warning labels for non-smokers (n=195) and smokers (n=113)

Label	Image themes	Graphic label M (SD)	Text label M (SD)	Label effect F	Label effect η_p^2	Non-smokers M (SD)	Smokers M (SD)	Smoker status effect F	Smoker status effect η_p^2
Cigarettes are Addictive									
Hole in Throat	D	3.97 (1.26)	2.74 (1.36)	128.61***	0.48	3.84 (1.04)	2.52 (1.30)	61.01***	0.30
Cigarette Injection	M, A	3.22 (1.46)	2.74 (1.36)	21.91***	0.14	3.50 (1.22)	2.08 (1.26)	56.20***	0.28
Red Puppet	M, A	2.72 (1.38)	2.45 (1.30)	7.03**	0.05	3.06 (1.32)	1.86 (1.01)	46.39***	0.25
Woman in Rain	U	2.54 (1.34)	2.45 (1.30)	0.66	0.00	2.96 (1.31)	1.80 (0.98)	42.21***	0.23
Tobacco Smoke Can Harm Your Children									
Smoke Approaching Baby	C	3.86 (1.36)	3.31 (1.36)	23.58***	0.15	4.05 (1.04)	2.78 (1.47)	45.00***	0.25
Smoke at Baby	C, A, U	3.84 (1.32)	3.31 (1.36)	24.61***	0.15	4.02 (1.07)	2.81 (1.41)	42.20***	0.23
Girl with Oxygen Mask	C, S, E	3.64 (1.34)	3.31 (1.36)	10.36**	0.07	3.94 (1.07)	2.69 (1.41)	49.84***	0.26
Smoke at Toddler	C	3.64 (1.46)	3.13 (1.38)	34.23***	0.20	3.80 (1.26)	2.72 (1.40)	28.91***	0.17
Girl Crying	C, S	3.30 (1.48)	3.13 (1.38)	2.76	0.02	3.66 (1.30)	2.53 (1.34)	34.52***	0.20
Child Lettering	A	3.09 (1.52)	3.13 (1.38)	0.11	0.00	3.57 (1.34)	2.43 (1.35)	28.60***	0.17
Cigarettes Cause Fatal Lung Disease									
Healthy/Diseased Lungs	D	3.92 (1.20)	2.99 (1.27)	85.97***	0.39	3.81 (1.12)	2.88 (1.20)	28.58***	0.17
Toe Tag	S	3.70 (1.33)	3.23 (1.35)	27.68***	0.17	3.90 (1.11)	2.71 (1.37)	40.46***	0.23
Lungs Full of Cigarettes	M	3.45 (1.34)	3.23 (1.35)	5.13*	0.04	3.81 (1.14)	2.55 (1.29)	44.33***	0.24
Doctor with X-Ray	E	3.07 (1.31)	2.99 (1.27)	1.13	0.01	3.46 (1.23)	2.38 (1.11)	35.84***	0.21
Cigarettes Cause Cancer									
Deathly Ill Woman	S	4.29 (1.06)	3.30 (1.41)	97.21***	0.41	4.16 (0.97)	3.16 (1.38)	35.34***	0.20
Cancerous Lesion on Lip	D	4.11 (1.13)	3.04 (1.39)	89.46***	0.39	4.00 (1.13)	2.93 (1.17)	45.45***	0.25
White Cigarette Burning	A	3.48 (1.44)	3.30 (1.41)	3.17	0.02	3.85 (1.18)	2.59 (1.46)	37.26***	0.22
Red Cigarette Burning	A	3.33 (1.33)	3.04 (1.39)	9.99**	0.07	3.62 (1.31)	2.53 (1.16)	34.38***	0.20
Cigarettes Cause Strokes and Heart Disease									
Oxygen Mask on Man's Face	S,E	3.63 (1.34)	3.03 (1.32)	35.04***	0.20	3.80 (1.17)	2.64 (1.24)	42.05***	0.23
Hand with Oxygen Mask	E	3.35 (1.38)	3.22 (1.37)	2.49	0.02	3.75 (1.15)	2.49 (1.35)	41.35***	0.23
Man in Pain-Hand on Chest	S	3.25 (1.34)	3.03 (1.32)	8.26**	0.06	3.60 (1.24)	2.48 (1.15)	38.10***	0.22
Red Lightening with Heart	A	3.15 (1.38)	3.22 (1.37)	0.61	0.00	3.67 (1.16)	2.39 (1.32)	38.69***	0.22
Smoking During Pregnancy Can Harm Your Baby									
Baby in Incubator	C,A,S,E	3.54 (1.51)	3.21 (1.48)	12.20***	0.08	3.74 (1.36)	2.79 (1.52)	17.69***	0.11
Pacifier in Ashtray	M	3.68 (1.42)	3.46 (1.36)	3.52	0.02	4.09 (1.04)	2.67 (1.46)	51.78***	0.27
Smoking Can Kill You									
Man with Chest Staples	S,D	3.81 (1.36)	3.32 (1.43)	27.40***	0.17	4.07 (1.14)	2.69 (1.39)	52.67***	0.28
Red Coffin with Body	A	3.47 (1.43)	3.32 (1.43)	2.38	0.02	3.94 (1.16)	2.45 (1.36)	55.26***	0.29
Man in Casket	S	3.33 (1.46)	2.98 (1.41)	16.08***	0.11	3.68 (1.35)	2.45 (1.24)	36.42***	0.21
Cigarettes=RIP	A	3.05 (1.42)	2.98 (1.41)	0.14	0.00	3.61 (1.33)	2.17 (1.10)	53.03***	0.28
Tobacco Smoke Causes Fatal Lung Disease in Non-smokers									
Graveyard	M	3.55 (1.41)	3.15 (1.50)	12.53***	0.08	3.89 (1.20)	2.46 (1.42)	51.74***	0.27
Man Smoke at Woman	U	3.52 (1.38)	3.15 (1.50)	16.24***	0.10	3.87 (1.16)	2.43 (1.44)	47.99***	0.26
Woman Crying	S	3.44 (1.39)	3.15 (1.50)	8.63**	0.06	3.85 (1.17)	2.36 (1.41)	53.57***	0.28
Woman Smoke at Man	U	3.03 (1.43)	2.95 (1.40)	0.39	0.00	3.55 (1.36)	2.20 (1.08)	48.60***	0.26
Man Hands Up And Smoke	U	3.02 (1.47)	2.95 (1.40)	0.06	0.00	3.57 (1.32)	2.14 (1.12)	58.47***	0.30
Quitting Smoking Now Greatly Reduces Serious Risk to Health									
Cigarettes in Toilet Bowl	M	2.69 (1.40)	2.71 (1.39)	0.21	0.00	3.13 (1.36)	2.03 (1.20)	25.72***	0.16
Man in 'I Quit' T-Shirt	M	2.47 (1.30)	2.51 (1.26)	0.31	0.00	2.83 (1.32)	1.98 (1.01)	21.26***	0.13
Woman Blowing Bubble	M	2.13 (1.24)	2.51 (1.26)	15.03***	0.10	2.63 (1.34)	1.84 (0.92)	20.59***	0.13

Response scale ranged from 1 (not at all) to 5 (very much). Image themes: A, art-graphics; C, child/baby; D, diseased body part; E, medical equipment; M, metaphor; S, suffering or dead person; U, unpleasant smoking experience. η_p^2=proportion of variance explained. The labels selected by the Food and Drug Administration in June 2011 appear in bold.
*p<0.05, **p<0.01, ***p<0.001.

information that the warning label effects extend to non-smokers and even have stronger effects on fear-related reactions and discouragement from smoking for non-smokers than for smokers. Nonnemaker and colleagues used a between-subjects design in which each participant viewed only one label, which enabled them to test the effects of each label on intentions to quit or to start smoking. Participants in the present study viewed multiple labels, and this experience may reflect the exposure to multiple (although potentially not as many) labels that community members will have when the labels are implemented and disseminated through media. Nonnemaker and colleagues also assessed general quit intentions (eg, 'How likely do you think it is that you will try to quit smoking within the next 30 days?'), whereas this study focused specifically on how the

labels affected motivations to not smoke. This distinction is important given that the previous study did not obtain evidence that the warning labels had much impact on smoking intentions; only three labels had reliable effects on smoking intentions for one of their subsamples, and those effects were small. In contrast, we found reliable and typically medium or large effects of the labels in discouraging respondents from wanting to smoke, suggesting that the labels may influence immediate smoking motivations.

Finally, our study added complementary evidence to findings from the previous studies .in that we compared the graphic labels to text-only labels that were similar in size and the use of red, black and white colour fonts in order to provide a strong test of the relative effects of the graphic images. The FCTC calls for the implementation of large warning labels on tobacco products, and the present findings support the use of the graphic images over large, text-only labels. Nonnemaker and colleagues provided complementary evidence on the size of proposed labels' effects on emotional responses relative to text-only statements in the size and font of current labels.

Several aspects of the study warrant comment. While the study sample included young adults from across the USA, recruitment through university-based distribution lists and MTurk means that the generalisability of the findings remains to be established. Use of these recruitment methods was necessary given the time constraints created by the need to complete the survey before the FDA selected the final set of labels and announced them to the nation. MTurk has been found to yield high-quality data, as reflected by such indicators as high-scale reliabilities that are comparable to those obtained through more traditional methods,[38] and it provided a diverse sample of young adults. Further research is needed to evaluate the effects of the labels for those communities not well-represented by this sample, particularly Hispanics and Latinos and those without high school diplomas.

The study utilised a heterogeneous sample of young adults ages 18–30, and it is possible that some subgroups could react differently to the graphic warning labels. For example, non-smokers at the older end of the spectrum may be less likely than younger non-smokers to initiate smoking in the future.[39] Although analyses revealed no age differences in immediate worry and motivational reactions to the labels, warning labels discouraging smoking may, nevertheless, have less impact on smoking initiation rates for older non-smokers than for younger non-smokers. Further studies utilising larger samples and additional measures of subsequent smoking behaviour are needed to examine age-related differences in immediate and longer term emotional, motivational and behavioural reactions to the labels.

One limitation is that participants viewed the warning labels on computers rather than in tactile, real-world settings. Interacting with tobacco warnings in naturalistic settings might lead to different (potentially increased) effects on fear-related reactions and discouragement from smoking. Although the use of multiple comparisons increases the risk of Type 1 error, the many large effect sizes and highly consistent patterns for the Label and Smoking Status main effects suggest that they are not due to chance. We split the graphic labels into two sets to reduce participant burden, leaving open the possibility that the other warnings in each set may have differentially influenced how each warning was rated. The random orderings should have minimised these effects and no set effects were observed for the text-only labels, but an alternative approach would be to randomise participants to 18 of the 36 labels. The few Label×Smoking Status interaction effects, which had small effect sizes and inconsistent patterns, should be interpreted with caution. The general absence of significant interaction effects suggests that the labels' main effects tend to be comparable for young adult smokers and non-smokers.

At the time of writing, the implementation of the labels was blocked by ongoing litigation (R.J. Reynolds Tobacco Co. vs U.S. FDA, No. 11–1482 (D.D.C.), on appeal, No. 11-5332 (D.C. Cir.). The original court decision found that requiring tobacco companies to display the labels violated their right to free speech. The ruling was upheld on appeal, and the FDA subsequently petitioned for its review by a large panel of judges. This litigation underscores the continuing need for research on the effects of the proposed warning labels and other graphic labels on knowledge and appreciation of the health consequences of smoking and on decisions to initiate, continue or quit smoking. This research also continues to inform the decisions of other countries regarding the implementation of graphic warnings as well as the development and selection of specific warnings.

In conclusion, the present findings indicate that, for young adult smokers and non-smokers, many of the proposed warning labels were easy to understand, enhanced fear-related reactions about the health consequences of smoking and discouraged them from wanting to smoke. The findings point to the types of images that may have the greatest effects in discouraging smoking: those with photographs of diseased body parts, suffering people, dead people, children and babies. The study also identified images least likely to influence smoking motivations: those with art graphics, metaphors or unpleasant smoking experiences. These findings can be useful in guiding the development of new labels in the future. The Family Smoking Prevention and Tobacco Control Act permits changes in the labels if they promote greater appreciation of the risks associated with smoking and reduce habituation to the warning labels that are in use. Further research could use larger samples of warning labels to provide sufficient power to test for the independent associations of the image themes with the variance in reactions accounted for by the graphic label effects. This research can also evaluate differences in use of images within a warning category, such as the relative influences of an image of a child or baby versus an adult in labels about the consequences

What this paper adds

▶ In 2011, the US Food and Drug Administration (FDA) proposed 36 new graphic warning labels for cigarette packages. This experimental study provides evidence that most of these labels, including all but one of the nine labels the FDA finally selected in 2011, effectively induced greater fear-related reactions and discouragement from wanting to smoke than corresponding text-only labels did for a sample of young adults in the USA.

▶ The graphic warning labels compared with text-only labels induced greater fear-related reactions and discouragement for both smokers and non-smokers, but these effects were stronger for non-smokers.

▶ The findings suggest that warning labels with photographs and images of diseased body parts, corpses or suffering people are likely to be more impactful than labels with art graphics, metaphorical images or depictions of unpleasant smoking experiences in eliciting fear-related reactions and discouraging viewers from wanting to smoke.

of secondhand smoke. Continued research is needed to further delineate the types of graphic images that have the greatest impact on risk perceptions and smoking motivations.

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Systematic Reviews

A systematic review of the perceptions of adolescents on graphic health warnings and plain packaging of cigarettes

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Abstract

Background: Graphic health warnings on tobacco packaging and the plain packaging of tobacco products are key tobacco control interventions. This systematic review investigates the perceptions of adolescents towards these packaging interventions.

Methods: Published, original-research, English-language articles from 1 January 2000 to 1 September 2017 were identified through a systematic literature search of the PubMed, CINAHL, PsycINFO, Web of Science, and Scopus databases. Articles describing investigations into the perceptions of adolescents aged 11 to 19 years towards graphic health warnings and/or plain-packaged cigarettes were included in this review.

Results: Nineteen articles, involving 15,935 adolescent participants, of which 72.85% were non-smokers or ex-smokers and 27.15% occasional or daily smokers, met the eligibility criteria. Graphic health warnings were perceived as more effective than text-only warnings, with warnings depicting lung cancer, and oral diseases being perceived as particularly effective. Health warnings increased viewer fear, anxiety, shock, and guilt and were considered effective in preventing non-smokers from experimenting with tobacco and prompting current smokers to quit. Plain packaging reduced the attractiveness and other positive attributes of cigarette packaging, with darker colours found to be the most effective. When used in combination, plain packaging increased the visibility of graphic health warnings, with participants also perceiving them as having an increased tar content and having more serious health risks, and increased thoughts of quitting amongst smokers.

Conclusions: Graphic health warnings and plain packaging appear to increase adolescent awareness of the dangers of tobacco use. Further research into the most effective warnings to use in combination with plain packaging is needed to ensure the greatest reduction in tobacco use and prevent tobacco-attributable morbidity and mortality in this vulnerable population.

Keywords: Tobacco control, Public health, Youth, Health literacy

Background

Tobacco use continues to be a major contributor to global morbidity and mortality, being responsible for an estimated 7 million deaths per year, and the attributable cause of death for over half of persistent tobacco users [1, 2]. Multiple forms of cancer and cardiovascular and respiratory diseases are the adverse outcomes of greatest concern, with their risk and severity being influenced by individual patient factors, alongside the cumulative exposure to carcinogenic constituents over the lifetime of a smoker [3, 4]. Therefore, initial tobacco experimentation and the development of nicotine addiction during the formative years when the brain is still maturing is linked not only to more significant risks to long-term health, productivity, and life expectancy, but also to a greater tendency to continue the addiction into adulthood [5, 6]. Physiological and sociological differences to adult populations increase the likelihood of addiction, where adolescents can experience significant peer pressure to experiment with drugs such as tobacco, which

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contributes to the majority of active adult smokers having started smoking during their teenage years [7, 8].

This issue is compounded by a long history of tobacco industry marketing tactics targeting adolescents and young adults in preference over older adults, as they are vital to the survival of the industry as the next 'generation' of smokers [9–12]. Whilst tobacco manufacturers have insisted that their packaging and other marketing techniques are meant only to retain brand loyalty amongst adult smokers, internal tobacco manufacturer documents show otherwise [9–12]. These targeted marketing strategies are the product of decades of research into attractive colours, shapes, logos, and descriptors meant to appeal to and attract adolescents and young adults, and create brand loyalty early in the life of a smoker [9–14]. The use of attractive packaging, filters, and variant descriptors such as 'light', 'mild', and 'smooth' have been shown to create misconceptions amongst both smokers and non-smokers on the relative safety of different cigarette brands and variants within brands [9–11].

In response to these marketing strategies, and to curb the use of tobacco amongst adolescents, there have been a range of interventions and programs implemented, including tax increases, banned point-of-sale advertising, mass media campaigns, and school- and parental-based educational programs. As part of the World Health Organization's Framework Convention on Tobacco Control (FCTC), articles 11 and 13 relate to the packaging and labelling of tobacco products, and tobacco advertising, promotion, and sponsorship respectively [15]. These aim to guide FCTC signatories in removing misleading impressions created by tobacco marketing, advertising, and branding and to ensure the use of sufficiently sized text and pictorial health warnings, to inform and educate the public on the dangers of tobacco use [15].

Countries implementing these bans make tobacco packaging one of the last available methods for tobacco manufacturers to promote their products and differentiate them from competitor's products [16, 17]. However, even this 'last bastion' for advertising is being increasingly controlled, through mandated pictorial and graphic health warnings, and the standardised (plain) packaging of tobacco products, first introduced in Australia in late 2012, and now present and planned for introduction in several other countries [18]. Reviews evaluating the effectiveness of these recent implementations of graphic health warnings (GHW) and plain packaging (PP) have been ongoing, with the growing body of international evidence supporting their use [18–22]. However, no review to date has focused on the effects of these interventions on adolescents. This systematic review therefore aims to assess the perceptions of adolescents towards graphic health warnings and plain packaging of cigarette packaging, which are aimed at reducing tobacco use

amongst this vulnerable population. We had significant interest in identifying how younger persons perceive tobacco use as a measure of social standing, the potential for harm caused by tobacco use, and how these perceptions were influenced by the packaging of tobacco products. This review aimed to answer the question: *How does tobacco packaging and labelling influence adolescents' perceptions of tobacco products?*

Methods

This review was conducted as part of a larger research project, using a protocol that is not currently published. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines were used as a reporting guide for this systematic review [23] (see Additional file 1).

Eligibility criteria

Eligible articles were those that gathered the self-reported perceptions of adolescents towards cigarette packaging which were either plain-packaged, displayed graphic health warnings, or both. These perceptions include any reported measure relating to perceived risks and attractiveness of packaging, as well as perceptions of the packs themselves, or smokers who use the packs. For this review, the relevant adolescent age was considered as being between the ages of 11 and 19 years old. This is the general age range of adolescents enrolled in middle school and high school, and where the use of tobacco generally becomes of concern within educational systems. Original-research articles published between 1 January 2000 and 1 September 2017, in the English language, were eligible for inclusion, whereas reviews, opinions, letters, and protocols were excluded. Articles which discussed the perceptions of young adults (18 to 35 years) or adults only were excluded, as well as those that did not differentiate data collected between different age groups if both adolescent and adult participants were enrolled. Other reasons for exclusion included the presentation and evaluation of text-only warnings on tobacco products, studies which did not gather self-reported adolescent participants' perceptions (such as eye-tracking studies), studies that did not include GHW and PP perceptions as their primary outcome measure, and studies which asked participants to recall warnings they had seen in day-to-day life.

Search strategy and study selection

Eligible articles were identified through a systematic literature search of the PubMed, CINAHL, PsycINFO, Web of Science, and Scopus databases. Searches utilised MeSH terms and combinations of the following words and their appropriate iterations: adolescent, perception, cigarette, plain packaging, graphic health warning, belief,

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behaviour, smoking, tobacco, warning, and young (see Additional file 2 for the detailed search strategy). Two authors (AD and BMA) were independently involved in article searching and screening and cross-checked each other's final lists of eligible articles. Disagreements relating to article eligibility were resolved by consensus amongst all four authors. Titles were read to identify potentially relevant articles, and we initially included any article that appeared to present cigarette packaging to participants of any age or smoking status. Abstracts were reviewed, and articles which involved adolescent participants' responses to cigarette packaging were retained, and those that matched the exclusion criteria were removed from the review. Eligible articles had their citations (using Google Scholar) and reference lists scanned to identify additional articles.

Data extraction and quality appraisal

Data extraction was initially performed by a single author (AD), then independently cross-checked by a second author (BMA). Data extracted from eligible articles included author details, year published, country of participant origin, participant numbers and age range, gender distribution, smoking status, study design, interventions employed, and outcomes reported. The primary outcomes of interest for this review were the perceptions of adolescents towards cigarette packaging that displayed graphic health warnings, were plain packaged, or both. Responses gathered included 'choice preferences' and Likert-scale ratings of packaging attractiveness, perceived cigarette taste, perceived health risks, warning intensity, perceived smoker attributes, preferred pack selection, personal relevance of warnings, and perceived effectiveness in preventing smoking in non-smokers and prompting current smokers to quit. Study quality was assessed using validated checklists from the Joanna Briggs Institute (JBI). The JBI 'Checklist for Analytical Cross Sectional Studies' was used for 16 studies [24], and the JBI 'Checklist for Randomized Controlled Trials' was used for three studies [25]. These checklists assess for study clarity, appropriateness of methodological design, analysis, presentation of results, and alignment of results and discussion to research objectives.

Data analysis

All outcome items were listed in a database, separated by type of intervention (GHW, PP, or both). Commonly described outcome items across the eligible articles (such as attractiveness of packaging for plain packaging studies, and perceived health risk across warnings for graphic health warning studies) were compared and reported relative to the intervention employed. Choice-based preferences and Likert-scale ratings which were identical or considered similar by authors (such as 'appeal' and 'attractiveness') were compared and pooled when describing

the perceptions of adolescents to give clarity to the overall findings of each intervention type. Other findings relating to adolescent perceptions, such as the opinions of participants towards cigarette packaging warnings, were recorded separately and used to support the primary outcomes. The results of studies which did not receive a high quality score during the quality assessment were taken into consideration and are identified within the results.

Results

Study characteristics

Figure 1 illustrates the resulting number of eligible articles from the search strategy. The search strategy initially identified 576 potentially eligible articles (after duplicates were removed), which was reduced to 90 after abstract reading. Full texts were then read, resulting in a final number of 19 eligible articles. Common reasons for ineligibility were participant population being young adults, lack of distinguishing results between adolescents and older participants, queried participants on their perceptions without presenting interventional materials, displayed text-only warnings on cigarette packaging, or presented television/mass media warnings.

Table 1 details the study and participant characteristics of each article included in this review. A total of 15,935 participants were included in the 19 studies reviewed, 7267 (45.46%) of which were male, 8659 (54.58%) female, and 9 (0.06%) not-stated, all between the ages of 11 and 19 years. Nearly three quarters (72.85%) of participants were non-smokers or ex-smokers, and the remainder (27.15%) were occasional or daily smokers. Seven studies were conducted in Europe ($n = 6150$), one in Oceania ($n = 1087$), three in Asia ($n = 4130$), six in North America ($n = 2958$), one in Africa ($n = 544$), and one both in Europe and North America ($n = 1066$).

The 19 eligible studies used either face to face or electronic means to gather quantitative data from participants. This data included participant perceptions of a range of interventional materials involving cigarette packaging, including their perceptions of health risks and tar delivery, pack attractiveness, smoker attributes, pack attributes, personal relevance of warnings, and warning credibility. For the purposes of this review, pictorial and graphic health warnings, testimonials, and lived experiences will be grouped under and abbreviated as GHW, and plain packaging (including plain white and plain brown packs) will be abbreviated as PP. Nine studies evaluated perceptions towards different GHWs [26–34], seven evaluated perceptions towards branded versus PP cigarette packages [35–41], and three evaluated perceptions towards a combination of GHWs and PP [42–44].

Fig. 1 Flow chart of systematic literature search
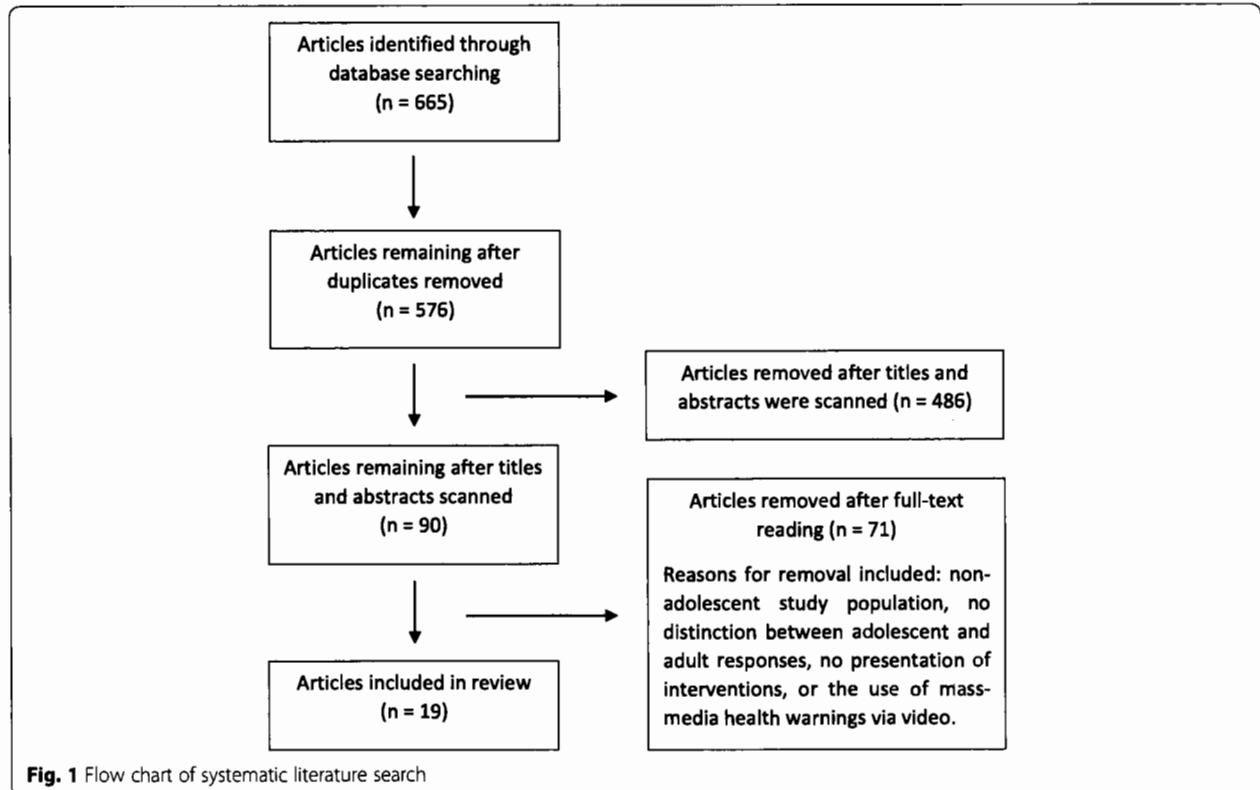
Quality appraisal

Sixteen studies were assessed by the JBI 'Checklist for Analytical Cross Sectional Studies' and scored out of eight, with four or below indicating low quality, five to six as moderate quality, and seven to eight as high quality [24]. Fourteen were found to be of high quality, and two of moderate quality [30, 32]. Three studies were assessed by the JBI 'Checklist for Randomized Controlled Trials' and scored out of 13, with seven or below indicating low quality, eight to ten as moderate quality, and ten and above as high quality [25]. All three RCTs scored were of high quality [42–44]. Table 2 details the quality appraisal outcomes of each study and the responses of participants to their respective interventional materials.

Graphic health warnings

Graphic image versus text warnings

Nine studies in this review reported on adolescent perceptions on the effectiveness of text warnings compared to GHWs [26–28, 30, 31, 34] and/or between different GHWs on cigarette packaging [28–34]. GHWs were perceived as more effective than text warnings across most outcome measures in these studies. This included their ability to communicate the negative health effects of smoking [26–28, 30, 34], prevent non-smokers from smoking [26–28, 31], and motivate current smokers to

quit [27, 28]. Two studies gathered specific reactions towards warning type, with graphic warnings considered more useful, credible, personable, and noticeable compared to text warnings and more capable in arousing fear and influencing a reader's self-efficacy in changing their smoking behaviours and discussing smoking with others [28, 31]. One study found no difference in participants' perceptions of text warnings vs. text plus pictorial warnings, though we considered the pictures used in the study as not being as graphic in comparison to warnings utilised in other studies [30]. This study also found that nearly half of participants did not believe that they would develop lung cancer if they became regular smokers, and nearly one third holding this belief relating to smoking and addiction. However, this study received a 'moderate' quality score during quality assessment, with issues such as ambiguity in the questions asked to participants potentially affecting the accuracy of these findings [30].

Standout and poorly rated graphic images

When comparing multiple GHWs, most studies identified that GHWs depicting respiratory or lung cancer were perceived as the most effective compared to other GHWs [26, 27, 30–32]. Studies that aimed to gauge specific reactions towards diseases portrayed in GHWs found that lung cancer and an increased perceived graphicness of warnings resulted in higher ratings for

Table 1 Participant and methodological characteristics of articles eligible for inclusion in this systematic review ($n = 19$)

Year published and main author	Location, participant numbers, and age range	Gender distribution		Participant smoking status			Mode of study and interventions employed	Data collection and outcomes reported
		M%	F%	NS%	EX%	S%		
2009 Hammond [35]	UK $n = 806$ 11–17 years	51.6	48.4	72.6	–	27.4	An online survey displaying six pairs of cigarette packs (using two brands), with branded, plain white, and plain brown packaging used, all displaying the same GHW.	Participants chose from each pair (or indicated 'no difference') which pack would have most tar delivery, smoothest taste, reduced health risks, highest attractiveness, and choice to smoke.
2009 Vardavas [26]	Greece $n = 574$ 12–18 years	46.0	54.0	80.6	–	19.4	An in-school digital survey using computer-generated images, displaying pairs of seven existing text-only warnings with a comparative proposed GHWs on un-branded packaging.	Participants rated warnings using 5-point Likert scales on perceived effectiveness in preventing smoking, depicting the impact of smoking on health, and perceived warning strength.
2010* Fong [27]	China $n = 396$ 13–17 years	50.8	49.2	87.9	8.1	4.0	Digitally constructed warnings were presented in person as photographs to adult and adolescent residents of four Chinese cities. Five pairs of cigarette packaging (four pairs with text-only versus GHW) were displayed.	Participants ranked and rated warnings using 5-point Likert scales on effectiveness in motivating smokers to quit, preventing youth smoking, informing the public on the harms of smoking, and showing government anti-tobacco initiative.
2010 Germain [42]	Australia $n = 1087$ 14–17 years	49.4	50.6	60.4	21.9	39.7	An online survey, with each participant randomly viewing one of 15 packs, varying in brand presented (3 brands), degree of brand prominence, and size of GHW (3×5 design).	Participants rated on 5-point Likert scales; five perceived pack attributes, five perceived smoker attributes, and seven perceived cigarette attributes.
2011 Hammond [36]	USA $n = 826$ 18–19 years	–	100	60.9	15.0	39.1	An online survey with participants viewing eight packages grouped into four categories: female-oriented brand with descriptors, female-oriented brand without descriptors, plain, and non-female-oriented brand.	Participants rated on 5-point Likert scales: brand appeal, brand taste, tar quantity, and health risks for each package. Participants also indicated on seven perceived attributes per pack (e.g. glamour, coolness, popularity) and their preferred pack.
2012a Hammond [28]	Mexico $n = 528$ 16–18 years	50.0	50.0	51.1	–	48.9	Face to face survey with participants viewing warnings from 2 of 15 health-effect themes, each of which contained 1 text-only, and 4 to 6 pictorial warnings. Each theme included; graphic health warnings, lived experiences, symbolic representations, and testimonials.	Participants rated 11 measures on 10-point Likert scales, including perceived message: credibility, personal relevance, and affective responses. Four of these 11 items related to perceived effectiveness, including motivating smokers to quit and preventing non-smokers from smoking.
2012b Hammond [37]	UK $n = 947$ 16–19 years	–	100	68.9	–	31.1	An online survey with participants assigned to one of four categories, each containing 10 cigarette packages: female-oriented brand with descriptors, female-oriented brand without descriptors, plain, and non-female-oriented brand.	Participants rated on 5-point Likert scales: brand appeal, brand taste, tar quantity, and health risks for each package. Participants also indicated on seven perceived attributes per pack (e.g. glamour, coolness, popularity) and their preferred pack.
2012 Moodie [38]	UK $n = 658$ 10–17 years	47.3	52.7	90.9	–	9.1	An online survey with participants viewing several colours of plain cigarette packs with a text 'Smoking Kills' warning (white, red, green, light blue), and a brown plain pack of standard, sliding, and super-slim designs.	Participants rated the four coloured packs on 5-point Likert scales their perceived taste and harm. The standard brown plain pack was rated on eight perception items (four pack and four smoker items), and preference compared to other designs.
2013 Ford [39]	UK $n = 1025$ 11–16 years	51.5	48.5	100	–	–	In-home surveys with participants viewing four branded packs (standard, slim, novel opening mechanism, and striking colour) and one plain pack with the same text warning.	Participants rated 11 items on 5-point semantic scales relating to package attractiveness, coolness, perceived harm, eye-catching, interest in smoking, and liking/disliking the pack.

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Table 1 Participant and methodological characteristics of articles eligible for inclusion in this systematic review (*n* = 19) *(Continued)*

Year published and main author	Location, participant numbers, and age range	Gender distribution		Participant smoking status			Mode of study and interventions employed	Data collection and outcomes reported
		M%	F%	NS%	EX%	S%		
2013a* Hammond [29]	USA *n* = 510 16–18 years	52.4	47.6	69.2	–	30.8	An online survey with participants randomly assigned to view two of nine sets of GHWs proposed by the FDA (6–7 warnings per set), with each GHW per set displaying the same text warning.	Participants rated several warning aspects on 10-point scales, including increase in concerns of health risks, efficacy motivating smokers to quit and preventing youth from smoking, and overall warning effectiveness.
2013b Hammond [43]	UK *n* = 762 11–17 years	54.9	45.1	93.8	1.0	4.9	An online survey with participants viewing six pairs of packs, comparing a regular pack to white or brown plain packs with moderate-sized text or graphic warnings (40%), or large-sized (80%) graphic warnings (2 × 3 model).	Participants selected from each pair (or indicated 'no difference') which pack would have most tar delivery, smoother taste, reduced health risks, highest attractiveness, would prompt to start smoking, and choice to smoke.
2013 Pepper [30]	USA *n* = 386 11–17 years	100	–	100	–	–	An online survey with participants randomly viewing one of four pack categories: addiction text-only warning, addiction text and image, lung cancer text-only warning, and lung cancer text and image (2 × 2 model).	Participants rated 5-point scales the perceived effectiveness of their warning in discouraging them from smoking, and the perceived likelihood and severity of suffering from the described condition (addiction or lung cancer).
2015* Alaouie [31]	Lebanon *n* = 1412 13–18 years	42.9	57.1	90.4% ex-smoker or non-smoker		9.6	Face-to-face interviews across 28 schools and universities, with students presented with two of five GHW on plain white packs compared to a locally available text-only warning.	Participants rated on 5-point Likert scales their perceived: message usefulness, noticeability, susceptibility, effectiveness, fear-arousal, self-efficacy in changing behaviour, intentions to not-smoke, and influencing family and close-contacts.
2015 Babineau [40]	Ireland *n* = 1378 16–17 years	55.7	43.7	78.6	4.2	17.2	In-school surveys for students across 27 schools. Pairs of packaging for three brands were presented. Packs were either branded or plain, with identical GHWs (lung damage).	Participants chose one pack (or indicated 'no difference') from each pair based on pack attractiveness, perceived health risks, perceptions of popular smoker attributes, and pack preference.
2016 Adebiyi [32]	Nigeria *n* = 544 13–17 years	44.7	55.3	98.3	–	1.7	In-school surveys in two schools in a single community, with participants viewing four GHWs: smoking harming children, and causing airway cancer, stroke, and impotence.	Participants indicated if each warning evoked: fear; shock, anxiety, or indifference. They also utilised a 3-point Likert scale on the effectiveness of each GHWs in preventing smoking initiation.
2016 Andrews [44]	USA, Spain, France *n* = 1066 13–18 years	50.0	50.0	–	–	100	An online survey with participants viewing one of eight packs (four plain and four branded) with varying levels of graphicness of GHWs, depicting the risks of smoking causing mouth cancer (2 × 4 model).	Participants rated using 6- and 7-point scales in response to the pack their: cigarette cravings, evoked fear (4 items), pack feelings (3 items e.g. embarrassed), and thoughts of quitting (4 items).
2016 Mutti [41]	Mexico *n* = 359 16–18 years	48.5	51.5	42.9	–	47.1	A face-to-face electronic survey with participants viewing a set of 12 gender-specific packs that were either fully branded or plain with brand name and descriptors.	Participants rated (yes/no/no difference) each pack on appeal, perceived taste, and perceived harm, with perceived smoker traits also rated (e.g. femininity, glamour, coolness, and popularity).
2016 Netemeyer [33]	USA *n* = 349 13–18 years	53.0	47.0	58.5	–	41.5	An online survey with participants randomly viewing one of nine cigarette packages containing a combined text and GHW.	Participants rated fear, guilt, and disgust evoked; perceived graphicness of the warning; and personal and perceived peer consideration of smoking after viewing.

Table 1 Participant and methodological characteristics of articles eligible for inclusion in this systematic review (*n* = 19) *(Continued)*

Year published and main author	Location, participant numbers, and age range	Gender distribution		Participant smoking status			Mode of study and interventions employed	Data collection and outcomes reported
		M%	F%	NS%	EX%	S%		
2017 Reid [34]	India, Bangladesh, China, Korea *n* = 2322 16–18 years	50.2	49.8	77.3	–	22.7^	Online survey in Korea and China, and computer-assisted interviews in India and Bangladesh. Participants viewed 2 of 15 sets of cigarette packaging warning. Each set included 5–6 warnings on the same consequence of smoking, and included one text-only warning, GHW, lived experience, and testimonial.	Participants were assessed on their perceptions of the potential health effects of smoking for all 15 sets of warning after viewing their randomly assigned two sets. Participants either 'agreed', 'disagreed', or responded 'do not know' to each health consequence listed.

GHW Graphic health warning Alaouie et al. [31]: smoking prevalence higher in males (18.2% vs. 3.4%)—statistics do not include narghile smoking
*Adult smokers participated in this study, though their results have been omitted in this review
^There were significant differences in smoking status between different countries (see Table 2)

inciting fear, guilt, and shock [32, 33]. Other GHWs of note included those that were increasingly graphic, those depicting foetal damage caused when smoking whilst pregnant [26], and those depicting oral diseases [27, 31, 33]. Impotence was the least effective of four warnings in one study, receiving the highest 'indifference' ratings by participants [32]. Skin ageing was also poorly rated in one study, with participants in only one of four countries having an increased awareness of this consequence of smoking [34]. Studies comparing methods for delivering GHWs also found that colour warnings were perceived as more effective than black and white warnings, those depicting real people as having a greater impact than those that were symbolic or cartoon-styled, and those that included quitline information over those that did not [28, 29]. Graphic images were perceived as more effective than symbolic or shared lived experiences, and those that depicted external rather than internal health effects [44].

Influencing participant characteristics
Some studies found significant differences in participant perceptions related to demographic characteristics, namely age, gender, and smoking status. One study found that female participants had significantly higher ratings for the warnings depicting foetal damage when smoking, and protecting children from cigarette smoke [26]. One study found that younger participants (those under 15 years) experienced higher levels of fear and shock and would be less likely to smoke when shown a warning depicting airway cancer (though the results of this study should be interpreted with caution due to receiving a moderate quality score) [32]. Smokers in particular reported higher levels of guilt with increased graphicness compared to non-smokers, though had lower levels of disgust towards graphic warnings [33]. In the two studies that asked participants relating to their overall perceptions of health warnings on tobacco products, a majority (> 75%) in both studies indicated that

cigarette packaging should include more health-related information, including the use of graphic images [27, 34].

Plain packaging
Overall perceptions of plain packaging
Seven studies investigated adolescent participants' perceptions of plain-packaged cigarettes, with most of the studies comparing white and/or brown plain-packaged cigarettes to fully branded, or partially branded packs (with or without accompanying health warnings) [35–41]. One study evaluated multiple colours of plain-packaged cigarettes [38], and one study evaluated plain-packaged cigarettes versus novelty branded cigarette packs [39]. In comparison to fully branded or partially branded packs, most of these studies identified that the brown-coloured, plain-packaged cigarettes were perceived by participants as having the lowest attractiveness/appeal, inferior taste, increased tar content, and an increased risk of causing ill-health [35–37, 39–41]. White packs were also perceived as less attractive and not preferred compared to branded packs in one study [35].

Impact of branding elements
Whilst some participants recognised that cigarette packaging does not influence health risk and tar delivery [35], a concerning theme which arose in some studies was the misperception that PP cigarettes had a lower tar content, reduced health risk, or were better tasting compared to branded cigarettes [35, 36, 38]. Colouration used when plain packaging cigarettes was found to be a critical aspect in one study, with half of participants associating the colour of the pack with cigarette harm and taste [38]. Whilst the brown plain pack was perceived as it was in other studies (unattractive, cheap, and uncool), the red pack was perceived as the strongest tasting and most harmful, whilst the white and light blue packs were perceived as being weaker tasting and the least harmful

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Table 2 Quality appraisal outcomes and study outcomes for each of the eligible studies (*n* = 19)

Year published and main author	Quality appraisal outcome	Intervention type* and analyses used	Key findings for adolescent perceptions of graphic health warnings and/or plain packaging^
2009 Hammond [35]	High (cross-sectional)	PP; chi-square, linear regression	• Both brands with plain white packs were perceived as less attractive, non-preferred, and having a lower tar content compared to the branded packs. • One pack brand was also considered as having a lower health risk, and one brand as having a less-smooth taste. • The plain brown packs were less attractive and less smooth for one brand, and less attractive, less smooth, higher risk, and non-preferred for the other brand compared to branded packs. All *p* values for these stated differences are < .001.
2009 Vardavas [26]	High (cross-sectional)	GHW vs. text warnings; chi-square, multivariate logistic regression	• GHWs were considered more effective than text-only warnings for 71.6 to 96.1% of participants, both in preventing non-smoking participants from smoking and in describing the effects of smoking on health. • Up to 84% of participants rated GHW as 'effective' or 'very effective' (4 or 5 out of 5) in preventing smoking initiation. • The GHW depicting lung cancer was rated as the most effective, followed by the GHW depicting foetal damage caused when smoking whilst pregnant. • Female participants had significantly higher effectiveness ratings of the GHWs depicting foetal damage, and protecting children from smoke (*p* < .05).
2010* Fong [27]	High (cross-sectional)	GHW vs. text warnings; chi-square, mixed-model ANOVA	• The four GHW packets were both rated and ranked as the most effective in motivating smokers to quit and preventing youth smoking, significantly higher than the six text warnings (*p* < .001), with the GHW depicting lung cancer rating the most effective, followed by the mouth disease, gangrene, and clogged arteries warnings (*p* < .05 between each warning). • The four GHW (with lung cancer as the highest rated) were also the most effective in informing the public on the dangers of smoking, with 81.5% of adolescents stating that packaging within China should contain more health information and 78.9% stating that packaging should include pictures instead of text-only warnings.
2010 Germain [42]	High (RCT)	GHW/PP; chi-square, ANOVA, principal component analysis	• Mean ratings of all positive pack, smoker, and cigarette attributes significantly reduced as branding and colour were progressively removed from packaging (*p* < .001), with 'lower class' perceptions concurrently becoming stronger (*p* = .043). • Smoking status was found to predict responses to pack ratings (*p* < .05), with established smokers having the most favourable perceptions of all packs. The addition of a larger GHW also had results dependent on smoker status, with experimenters and active smokers having the largest drop in perceptions of positive pack characteristics compared to susceptible and non-susceptible non-smokers (*p* < .01).
2011 Hammond [36]	High (cross-sectional)	PP; linear regression	• Compared to standard packs, of the eight brands used, plain packages were consistently the least appealing, were perceived as the worst tasting for six of the brands, had lower levels of tar for two of the brands, and were considered less harmful for two of the brands (all *p* < .05). • Plain packs also received significantly fewer positive ratings for every smoker trait (glamour, femininity, slimness, coolness, popularity, attractiveness, and sophistication) compared to standard packs (*p* < .001). • Significantly fewer participants preferred plain packs (*p* < .001).
2012a Hammond [28]	High (cross-sectional)	GHW; linear mixed effects models	• Text-only warnings were the lowest rated for all 15 health effects (*p* < .001), with the graphic warnings being rated as more effective than both the symbolic and lived experience warnings (*p* < .001), and those depicting external health effects perceived as more effective than those depicting internal health effects (*p* < .001). • Lived experience warnings that depicted effects on others were rated as more effective than those that depicted effects on oneself (*p* < .001), and susceptible non-smokers had significantly higher ratings than non-susceptible non-smokers (*p* = .02).

Table 2 Quality appraisal outcomes and study outcomes for each of the eligible studies (*n* = 19) *(Continued)*

Year published and main author	Quality appraisal outcome	Intervention type* and analyses used	Key findings for adolescent perceptions of graphic health warnings and/or plain packaging^
2012b Hammond [37]	High (cross-sectional)	PP; linear regression	• Plain packs received the lowest appeal (p = .013), and taste ratings (p = .027), were less likely selected as a preferred pack (p = .026), and were considered to have higher tar compared to the fully branded packs (p = .024). • Fully branded packs were also considered to have the lowest health risks compared to all other categories (p = .006). • For perceived smoker traits, plain packs received the lowest ratings for all seven attributes: femininity, slimness, glamorous, coolness, popularity, attractiveness, and sophistication (all p < .05).
2012 Moodie [38]	High (cross-sectional)	PP; chi-square	• Half of the participants associated colour and strength of taste, and colour and perceived harm, with the red pack considered the strongest tasting and most harmful and the light blue pack and white packs as weaker tasting and being the least harmful. • The brown plain pack was seen as largely unattractive, cheap, and uncool and used by boring, unfashionable, and older people. Smokers displayed less negativity towards the pack compared to non-smokers. • Smokers were more likely (p < .001) to prefer a pack, with the slide pack being the most popular of the brown plain packs.
2013 Ford [39]	High (cross-sectional)	PP; principal components analysis	• The mean ratings for all 11 items for all packs (e.g. attractiveness, coolness, harmfulness) were generally negative (none > 3 out of 5), with the plain pack being the most negatively rated, with mean scores ranging from 1.24 to 1.99 (p < .01). • The standard pack was also more negatively rated than the three novelty packs. • Unlike the branded packs, the plain pack showed no association between the 11 rated aspects, and smoking susceptibility.
2013a* Hammond [29]	High (cross-sectional)	GHW; linear mixed effects models	• Full-colour warnings were rated more effective than black and white warnings (p = .004), as were real people over comic book-style (p < .001), and those featuring quitline information (p < .001), particularly for current over non-smokers (p = .046). • Those with personal information were higher rated over those that did not (p < .004), as were those with graphic content compared to those that did not (p < .001), particularly for females over males. Mean scores were higher for 'minority race respondents' compared to 'white respondents' (p = .002).
2013b Hammond [43]	High (cross-sectional)	GHW/PP; chi-square, generalised estimating equation model	• Compared to branded packs, plain packs were considered less attractive, less likely to encourage smoking uptake, and had higher impact health warnings. Brown packs and those with graphic health warnings were also less likely perceived to have a smooth taste, present a lower health risk, or contain a lower amount of tar (all p < .001). • Larger GHWs were rated as the least attractive compared to moderate-size GHWs (p = .001) and text warnings (p < .001), were the least smooth tasting (p < .001 and p < .001 respectively), the least likely perceived to have a lower health risk (p < .001 compared to text warnings), the least likely perceived to have lower levels of tar (p < .001 and p < .001 respectively), and were perceived as having the highest impact on health (p < .001 and p < .001 respectively).
2013 Pepper [30]	Moderate (cross-sectional)	GHW; linear regression, ANOVA	• The lung cancer warnings (both text-only and text plus image) received higher ratings than the addiction warnings, with 60% of assigned participants rating them 5 out of 5 for discouraging smoking, compared to 34% for addiction warnings (p < .001). • There were no significant differences in deterring smoking or perceived risk for text vs. text plus image for either category. • Over half of assigned participants believed they would develop lung cancer if they smoked regularly, and over two thirds held this belief for developing nicotine addiction, with both categories also generally being considered as very severe.
2015* Alaouie [31]	High (cross-sectional)	GHW; McNemar test	• Participants perceived all GHWs as significantly more effective for all items compared to the text-only warning (p < .001). • Overall, compared to the text warnings, the lung cancer GHW received significantly higher effectiveness rating, followed by

Table 2 Quality appraisal outcomes and study outcomes for each of the eligible studies (*n* = 19) *(Continued)*

Year published and main author	Quality appraisal outcome	Intervention type* and analyses used	Key findings for adolescent perceptions of graphic health warnings and/or plain packaging^
			tooth decay, and death (all $p < .01$) except for female smokers due to low participant numbers. • All warnings were significantly more effective than text warnings (all $p < .001$) in preventing non-smokers from smoking.
2015 Babineau [40]	High (cross-sectional)	PP; chi-square, generalised estimating equation	• Two of the branded packs were perceived to be more attractive and healthier and used by 'popular' individuals, and were chosen twice as frequently compared to plain packs (all $p < .001$). • One pack brand (with pink and purple colouring) had a lower margin for choice ($p < .001$) and did not experience differences in attractiveness ($p = .08$), between the two packs, though the branded pack was perceived as healthier ($p < .001$). • Female participants were significantly more likely than males to associate this brand with popularity ($p = .03$).
2016 Adebiyi [32]	Moderate (cross-sectional)	GHW; bivariate analysis	• Responses to the four GHWs included fear in 37.3–56.4%, shock in 23.3–37.3%, anxiety in 2.9–21.1%, and indifference in 3.3–20.0% of participants. The GHW suggesting that smoking causes impotence had the highest indifference rating. • The GHW depicting airway cancer had the highest fear and shock ratings, and the lowest ratings for anxiety and indifference, and perceived as the most effective in preventing adolescents from smoking, especially those < 15 years ($p < .05$). • The GHW stating cigarette smoke harming children received the highest frequency of anxiety.
2016 Andrews [44]	High (RCT)	GHW/PP; multivariate analysis	• The two most graphic health warnings significantly increased thoughts of quitting, evoked fear, and reduced feelings towards the pack and cigarette cravings compared to the control and low-graphic health warning (all $p < .05$). • Plain packaging led to significant reductions in cigarette craving and feelings towards the pack ($p < .05$) and increased evoked fear ($p < .05$), but had no effect in increasing thoughts of quitting. • There were no combined effects overall for PP and GHWs, though there were some combined effects in France and Spain in reducing cravings and pack feelings respectively, though there were smaller cell sizes and reduced statistical power.
2016 Mutti [41]	High (RCT)	PP; chi-square, linear regression models	• Plain (with descriptor) packages received significantly lower ratings for appeal and taste (both $p < .001$) compared to branded packs, though there was no significant difference in perceptions of harm. • Female participants were more likely to give higher appeal and taste scores and rate packs as less harmful compared to males ($p < .001, < .001, = .02$ respectively). • Smokers were more likely to give higher taste ratings and consider packs as less harmful compared to non-smokers ($p < .05$). • Non-smokers rated branded packs significantly higher for all positive smoker-image traits (all $p < .05$), whilst smokers only rated two traits higher from branded compared to plain packs (stylish and sophistication, both $p < .05$). • Older adolescent participants also rated positive smoker-image traits higher than younger participants.
2016 Netemeyer [33]	High (cross-sectional)	GHW; linear regression models	• Perceived graphicness was associated with an increase in evoked fear and guilt ($p < .01$) for smokers and non-smokers. • Smokers had lower levels of disgust with increased graphicness compared to non-smokers. • Increased graphicness also led to increased hesitance (reduced personal consideration) towards smoking. • Stronger emotions in response to higher levels of perceived graphicness were more significant in smokers compared to non-smokers.
2017 Reid [34]	High (cross-sectional)	GHW; chi-square, ANOVA, logistic regression	• Perceptions of the health effects of smoking significantly increased for those who viewed the mouth cancer, heart disease, emphysema, and stroke (China and Korea), throat cancer (Bangladesh and Korea), skin ageing (India), impotence (India,

Table 2 Quality appraisal outcomes and study outcomes for each of the eligible studies (*n* = 19) *(Continued)*

Year published and main author	Quality appraisal outcome	Intervention type* and analyses used	Key findings for adolescent perceptions of graphic health warnings and/or plain packaging^
			China, and Korea), and gangrene (Bangladesh, India, and Korea) warnings (all *p* < .05).
			• Three quarters of participants in China, Bangladesh, and Korea and half in India also believed that cigarette packages should include more health-related information than the current packaging warnings were displaying in their respective country.

*GHW Graphic health warning (includes any form of pictorial warning, lived experience, and testimonials), PP plain packaging
^Results in these studies discussing adult participants, or adolescent perceptions of text-only warnings were excluded from this table

[35, 38]. However, one study found that for two of the brands presented, brown plain packs were perceived as having a reduced tar content and would cause less harm [35]. Smokers in one study also showed less negativity towards a brown plain pack compared to non-smokers [38]. Text descriptors on packaging (such as 'smooth' and 'gold') were also found to sometimes significantly influence participant perceptions when used on plain packs, perceiving them as containing less tar, having a lower health risk, and being more attractive [35].

Perceived pack and smoker attributes

Apart from comparisons of adolescent perceptions of cigarette quality and safety, several studies investigated perceptions of positive pack attributes, such as coolness, glamour, popularity, and femininity (for female participants). Akin to the perceptions of quality and safety, plain-packaged cigarettes were similarly the lowest rated for these measures compared to partially or fully branded packs [36, 37]. Perceived smoker attributes were also assessed in several of these studies, where participants rated their perceptions of a smoker of branded compared to plain-packaged cigarettes, with characteristics such as being cool, popular, attractive, and sophisticated being significantly lower than branded packaging [36–38, 40, 41]. Five studies also explored participants' views on their preferred pack, and plain packs were consistently the least likely to be chosen compared to both standard and novelty branded packs [35–37, 39, 40].

Influencing participant characteristics

Female participants were more likely to associate a pink and purple branded pack with a positive smoker attribute (popularity) in one study [40] and gave higher appeal and taste scores and lower harm scores compared to males in another study [41]. This study also found that smokers gave higher taste ratings and considered smoking to be less harmful, whilst non-smokers gave significantly higher positive ratings for all smoker-image traits [41]. Older adolescents in this study also rated positive smoker-image traits [41].

Combination of graphic health warnings and plain packaging

Three studies investigated adolescent perceptions of packaging with varied combinations of PP and GHW interventions [42–44]. Similar to the studies above evaluating the perceptions of either intervention used alone, GHWs increased perceptions of ill-health and thoughts of quitting, elicited fear, and reduced positive perceptions (such as attractiveness towards the pack), whilst PP also reduced packaging attractiveness, reduced intent to take up smoking, and affected perceptions of taste and tar content [42–44]. They also found that combining both types of intervention (the gradual removal of branding elements, and increased size or graphicness of GHW) led to further reduced positive pack perceptions [42, 43], and reduced cigarette cravings and pack attractiveness [44].

Influencing participant characteristics

Several perceptions were influenced by smoking status in two of the studies, whilst age and gender appeared to have no impact in any study. Smokers indicated higher positive perceptions towards all packs and a larger decrease in positive perceptions in response to large GHWs in one study [42], with another study's smokers rating packs as more attractive and having a smoother taste than non-smokers [43]. One study reported that the American participants showed no significant differences in response to the combination of PP and GHW, whilst their French and Spanish counterparts indicated a reduction in cigarette cravings and pack attractiveness [44].

Discussion

The objective of this systematic review was to identify and evaluate recent research investigating the perceptions of adolescents towards graphic health warnings and plain packaging of tobacco products. Participants in the 19 eligible articles generally perceived GHW as being effective in modifying their smoking behaviours and portraying the negative health effects of smoking compared to text warnings. PP was also perceived effective in contributing to an increased awareness of the health risks of

smoking and reducing the attractiveness, popularity, and coolness of packaging and smoking. These findings support the position of the World Health Organization to ensure 'consumers of tobacco products have a fundamental right to accurate information about the risks of smoking and other forms of tobacco use' [45]. Adolescent risk perceptions differ from those of adults and may be more likely to engage in risky behaviours with the potential to have an adverse effect on personal health, stemming from a combination of targeted marketing and peer effects experienced during adolescence [7]. This emphasises the need for the development of tobacco packaging interventions to consider population differences, to ensure reductions in tobacco use amongst both adolescents and adults [7, 46].

The 'Health Belief Model' is a theoretical framework which predicts health-related behaviours (such as tobacco use) as being influenced by multiple internal and external factors, such as the perceived susceptibility and severity of tobacco-attributable diseases, benefits and barriers in modifying behaviours, and cues and self-efficacy in changing these behaviours [47]. Therefore, by minimising the attractive branding aspects of tobacco products, whilst simultaneously drawing attention to the health risks associated with tobacco use, GHWs and PP may act as prompts to quit amongst smokers, minimise the prevalence of experimental and daily tobacco use amongst adolescents, and the resulting continued use of tobacco into adulthood [7, 8].

In this review, pictorial health warnings were consistently perceived as more effective than text-only warnings in communicating the health risks associated with tobacco use and modifying non-smoker and smoker behaviours [26–28, 30, 31, 34]. This is supported by a recent meta-analysis that included both adults and adolescents, which reported that pictorial warnings attracted more attention, caused strong reactions, incited more negative attitudes towards packaging and smoking, and were more effective in reducing tobacco use [19]. The increased size and 'graphicness' (also referred to as strengthening) of health warnings has also been found to be an important aspect of individual warnings, resulting in improved knowledge of the risks of tobacco use and intentions to quit smoking [20]. In this review, GHWs depicting lung cancer were perceived by participants as being the most effective, followed by those depicting oral diseases [26, 27, 30, 32]. In comparison to text-only messages, GHWs which clearly depict negative (particularly external) health consequences of tobacco use have been theorised to have a greater public reach as they require minimal levels of health literacy for basic understanding. This is made more important by the trend of increased smoking prevalence amongst those with a lower level of education [48–50]. However,

depicting short-term external health effects as opposed to longer-term chronic diseases may be more effective on adolescents, due to the 'remoteness' of conditions such as lung and mouth cancers [28, 51]. Further research is needed into the development of 'ideal' GHWs which can modify adolescent as well as adult perceptions and behaviours, especially considering some health effects in this review, such as skin ageing and impotence (believed to be very important to adolescents), were perceived as less effective than other GHWs [26, 32].

Similar to the findings in this review of the perceptions of adolescents towards plain packaging, a large systematic review (and a post-publication update) of both adolescents and adults identified significant reductions in packaging attractiveness as branding elements were removed [21, 22]. Perceptions of cigarette taste, safety, and quality and pack and smoker attributes were also consistent with the findings of this review [21, 22]. Though plain packaging was perceived as effective in influencing adolescent opinions of packaging and smoking when used alone, there were misperceptions identified amongst participants. Brightly coloured plain packaging can lead to perceptions of reduced tar content, reduced negative health consequences, and increased attractiveness of cigarette packaging [35, 38, 43]. Whilst the use of dark green/brown plain packaging initially implemented in Australia (and recently several other countries) may avoid this issue [18], some participants in one study perceived this colour as being less dangerous than branded packaging [36]. This emphasises the need for plain-packaged products to not only be dissuasively coloured, but also be accompanied by informative GHWs to ensure a reduction in pack attractiveness and increased perceived harm [36, 40]. The effects of PP regulations stem not only from its negation of attractive branding colours, but also via the removal of variant descriptors, meant to distinguish sub-types of cigarette products and attract and retain brand loyalty [9–11]. The banning of certain misleading descriptors such as 'light' and 'mild' has been an effective first step, though manufacturers have replaced these terms with others such as 'smooth' or 'gold advance', also capable of deceiving the public on the tar content, taste, and health risks of cigarettes [9–11].

Adolescent perceptions can be significantly influenced by demographic characteristics, such as smoking status, with several studies in this review reporting that current smokers (and to a smaller extent ex-smokers) were generally less affected by GHWs (and plain packs) compared to non-smokers [33, 38, 41, 42]. 'Optimistic bias' as described within these studies is a critical issue particularly amongst younger smokers, who believe themselves to be less vulnerable to the health consequences of smoking [33, 38, 41, 42]. As indicated earlier, future research should therefore focus on the development of targeted GHWs that can prompt cognitive reactions across a wide range of demographic profiles to facilitate

the highest reduction in tobacco use. This was demonstrated in some of the included studies, such as female participants having higher perceived effectiveness ratings of foetal damage from smoking [26], and higher attractiveness ratings of 'female-oriented' packaging [40].

As adolescence is often a time for experimentation and risk-taking behaviours, during which there can be a quick loss of autonomy (with some researchers positing that this can occur after the first use of tobacco), reducing the attractiveness and glamour of tobacco packaging whilst highlighting the dangers is paramount [52–54]. With regard to message framing, loss-framed messages dominate mass media and packaging warnings, describing the negative consequences of smoking, whereas gain-framed messages describe the benefits of not smoking, or quitting. Whilst previous research has identified that graphic loss-framed warnings can have a higher rate of recall, some evidence suggests adult smokers experience greater reductions in tobacco use when shown gain-framed warnings [55, 56]. Research into adolescent reactions to loss- versus gain-framed messages would be ideal in ensuring the implementation of the most effective combination of GHWs and PP.

Apart from issues relating to misperceptions of warning irrelevance and optimistic bias amongst adolescents, a recent study investigating the 6-month, 2-year, and 5-year effects of GHWs found that though there was an increase in cognitive processing of warnings post-implementation, the 5-year survey found that there was a subsequent decrease back to pre-implementation levels [56]. This finding alongside similar findings in adult participants demonstrates that GHWs are most effective shortly after implementation but suffer from a loss of effectiveness over time, requiring a constant updating or rotation of warnings [56, 57]. It has also been suggested that PP would inhibit the loss of effectiveness of GHWs [57]. Two other studies have assessed the real-world impacts of PP alone on adolescents. One study found that only one fifth of adolescents had noticed PP nearly a year after implementation [58], whilst the other found that participants demonstrated an increase in support for PP, never-smokers reported they would be less likely to try smoking, and current smokers reported increased thoughts about quitting [59]. Whilst some results of these studies into the effects of GHWs and PP are promising, it is difficult to distinguish changes in responses pre- and post-implementation from concurrent trends in tobacco use and anti-tobacco interventions such as taxation policies and mass media campaigns.

Further research into the perceptions of adolescents in comparison to adults towards graphic health warnings and plain packaging is needed to identify the most effective combination of these interventions, especially when used alongside other interventions, such as mass media campaigns. School- and parental-based intervention programs, which focus on health risks associated

with smoking displayed on cigarette packaging, may also be beneficial in reducing adolescent tobacco use [60].

Strengths and limitations

The large number and geographical spread of participants included in this review allows for an increased generalisability of these findings across different populations and cultures and may be of relevance to many countries hoping to implement or update their anti-tobacco policies. This review also has several limitations, such as being unable to extrapolate the results to young adults, though similar in age, may undergo several perceptual changes secondary to their coming of legal age in purchasing tobacco. Their exposure to environments in which tobacco use is considered more socially appropriate compared to the school environment (e.g. workplaces, bars, and university) may also lead to altered perceptions. The use of electronic and internet surveys in many of the studies have their own limitations, such as preventing participants from viewing realistic 3D objects and facilitating tactile sensations, potentially not drawing a representative sample of the population, and having the perceptions given by adolescents potentially affected by nearby persons, such as their parents or teachers. A single exposure to the interventional materials in these studies is also a noteworthy limitation, as the responses given by participants may not be reflective of real-world conditions of multiple exposures after time and the potential for a stagnation of effects. Lastly, self-reporting bias was identified as a limitation in many of the included studies, where adolescents may report what they believe the researchers want to hear, rather than their true perceptions.

Conclusion

Preventing tobacco use amongst adolescents and the resulting continued use into adulthood require the implementation of carefully designed and targeted anti-tobacco interventions. Dark-coloured packaging without branding elements and graphic health warnings depicting health consequences of smoking, such as lung cancer and oral diseases, appear to be perceived as more effective than bright-coloured packaging and those depicting other chronic tobacco-related issues respectively. As adolescents do not appear to perceive the threat of continued tobacco use in the same manner as adults, tailoring anti-tobacco interventions such as graphic health warnings and plain packaging towards this vulnerable population is essential in addressing adolescent tobacco use. Further research aimed at identifying the most concerning and emotion-responsive health conditions that could be depicted on packaging, in addition to plain packaging, would be a reasonable next step in anti-tobacco packaging interventions.

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Additional files

> **Additional file 1:** PRIMSA checklist. (PDF 197 kb)
>
> **Additional file 2:** Full search strategy. (DOCX 12 kb)

Abbreviations
FCTC: Framework Convention on Tobacco Control; GHW: Graphic health warnings; JBI: Joanna Briggs Institute; PP: Plain packaging; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Availability of data and materials
Data sharing is not applicable to this article as no additional datasets were generated or analysed during the current study.

Authors' contributions
AD carried out the systematic search and data extraction and analysis and was responsible for the drafting of the manuscript. PAT participated in the drafting of the manuscript. BG advised on article eligibility and inclusion and participated in drafting the manuscript. BMA assisted in the systematic search, identifying eligible articles, and assessing article quality and was responsible for reviewing the final draft of the manuscript. All authors have read and approved the final manuscript.

Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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Impact of *The Real Cost* Media Campaign on Youth Smoking Initiation

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Introduction: The purpose of this study was to assess the relationship between youth exposure to the U.S. Food and Drug Administration's national tobacco public education campaign, *The Real Cost*, and changes in smoking initiation.

Methods: From November 2013 to November 2016, a longitudinal study of youth was conducted with a baseline and 4 post-campaign follow-up surveys. The sample consisted of nonsmoking youths from 75 U.S. media markets ($n=5,103$) who completed a baseline and at least 1 follow-up survey. Exposure was measured by media market-level target rating points and self-reported ad exposure frequency. Smoking initiation was examined among youths who had never smoked at baseline and defined as first trial of a cigarette. Discrete-time survival models using logistic regression and controlling for confounding influences were estimated. Analyses were conducted in 2018.

Results: The odds of reporting smoking initiation at follow-up was lower among youths in media markets with higher levels of campaign advertisements than among those with less. Both between-wave and cumulative target rating points were associated with decreased risk of smoking initiation (AOR=0.69 [$p<0.01$] and AOR=0.89 [$p<0.05$], respectively); for every 3,500 between-wave target rating points on air, there was an associated 30% reduction in the hazard of smoking initiation among youths. Results from self-reported recall of the campaign advertisements found similar dose—response effects. The campaign is associated with an estimated 380,000—587,000 youths aged 11—19 years being prevented from initiating smoking nationwide.

Conclusions: Sustained national tobacco public education campaigns like *The Real Cost* can change population-level smoking initiation among youths, preventing future generations from tobacco-related harms.
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INTRODUCTION

Despite significant progress in reducing tobacco use in the U.S., smoking remains the leading cause of preventable disease and death; 480,000 people die annually from smoking-related illnesses.[1] Each year, approximately 733,000 youths smoke their first cigarette.[2] Public education campaigns have been found to reduce youth smoking prevalence by shifting beliefs about tobacco use, preventing initiation, and reducing progression to established smoking.[3-7] This empirical body of evidence from 2 decades of research have yielded guidance on identifying promising message strategies, developing advertisements that resonate with youth, and purchasing media to achieve sufficient campaign exposure within the intended audience.[8,9] Today,

media campaigns occur in a rapidly evolving media environment, requiring specialized audience targeting of advertisements to engage youth across multiple media channels. The extent to which current media campaigns successfully influence youth may differ from past generations of health campaigns,[10] and continued research on the effectiveness of education campaigns is critical to ensure they positively impact public health.

The Real Cost is a national public education campaign designed to prevent and reduce smoking among U.S. teenagers. The theme of the campaign—every cigarette costs you something—is conveyed through advertisements that highlight the health effects, toxicity, and loss of control associated with smoking.[11] Sponsored by the U.S. Food and Drug Administration's Center for Tobacco Products, *The Real Cost* is grounded in scientific evidence and behavior change theory.[8,9,12]

Advertisements have aired continuously at high media levels since the launch of *The Real Cost* in February 2014, resulting in high levels of campaign recall[13] and changes in tobacco-related beliefs nationwide.[14] A previous study found a positive dose−response relationship between youths' self-reported recall of *The Real Cost* advertisements and lower rates of smoking initiation.[15] However, self-reported exposure data are subject to measurement error. Using an exogenous measure of media dose, such as market-level target rating points (TRPs), is the most rigorous approach in natural experiments like media campaigns when control groups are unfeasible.[16−18] More broadly, the triangulation of findings regarding campaign effects using complementary exposure assessments is important in a complex media environment that includes multiple public tobacco-related campaigns and media channels.

This study is the first in a decade to assess a national youth media campaign's multi-year impact on smoking initiation using market-level exposure to TV and online advertisements. Data from a national cohort of youth were examined to explore the association between temporal and geographic variation in campaign exposure and initiation among youths between 2014 and 2016. Data from 5 waves of a longitudinal survey of U.S. youth were analyzed to determine whether campaign exposure influenced trial of cigarette smoking over 3 years among never smokers at baseline.

METHODS

Study Sample
Data were from a nationally representative longitudinal survey of U.S. youths aged 11−16 years at baseline. An address-based sampling frame, supplemented with market research data, was used to randomly draw households likely to have at least 1 eligible

youth (5% of households) in U.S. Census block groups within 75 media markets. In person baseline data collection took place from November 11, 2013, through March 31, 2014. Four subsequent surveys were collected during the following time periods either online or in person: first follow-up, July 24−October 27, 2014; second follow-up, April 6−July 4, 2015; third follow-up, December 17, 2015−April 5, 2016; and fourth follow-up, September 15−November 22, 2016. Participants received $25 for survey completion in the first 3 weeks and $20 thereafter. The baseline sample size was 6,743 youths; 4,210 youths completed all follow-up waves. The analytic sample included 5,103 youths who were nonsmokers at baseline and completed at least 1 follow-up wave. The study was approved by IRBs at the Food and Drug Administration and the researching institution.

At baseline, 7,418 sampled households were eligible to participate; 2,083 households with unknown eligibility were estimated to be eligible. Participants in 4,538 households completed a survey. The unweighted household-level response rate was 47.8%, and the weighted household-level response rate was 43.7% at baseline.[19] The person-level response rates for the 4 follow-ups, calculated as the percentage of the sample from the previous study wave, ranged from 84.9% to 91.4%.

The Real Cost was designed to encourage teens to reassess the costs of tobacco use. Advertising in the first year focused on short-term health effects and loss of control associated with smoking. Advertising in 2015 and 2016 continued these themes and introduced new messages about the toxic chemicals in cigarettes and health consequences using a humorous approach (Appendix Table 1, available online). Advertisements aired on national TV, radio, the Internet, out-of-home displays, in magazines, and at movie theaters. Campaign messages were also disseminated through social media and mobile gaming.

The standard unit of measurement for media delivery,[17,20] TRPs are calculated as the product of 2 measures, the percentage of a target population potentially exposed to advertisements (reach) and the average number of times advertisements may have been seen (frequency) over a time period. Youth in the study markets were exposed to the following mean values of cumulative TV TRPs and digital video TRPs, respectively: 2,451 and 609 (baseline to first follow-up), 2,976 and 937 (first to second follow-up), 2,768 and 1,012 (second to third follow-up), and 2,775 and 1,372 (third to fourth follow-up). The average weekly TV TRPs were 63 (range, 22−150); the average digital video TRPs were 22 (range, 10−50).

Measures
The primary outcome of interest was smoking initiation among youths who had never smoked at the time of the baseline survey (never smokers). Smoking initiation was defined as first trial of a cigarette among youths who had never used cigarettes.

Two TRP measures that combine TV and digital video TRPs were calculated for each respondent based on the designated market area where the individual lived and the timing of the respondent's surveys. Because media may take considerable time to influence smoking behavior, TRPs from the campaign launch through the date a respondent took each respective survey were aggregated. However, cumulative TRPs monotonically increase with a time trend during the study period. An alternative exposure specification shortens the timeframe over which TRPs are studied

to between each survey wave. Between-wave TRPs limit the media's measurable effect because older TRP exposures that may have reasonably affected future smoking initiation are excluded. However, it reduces the inherent association between TRPs and time in the cumulative measure.

After viewing each advertisement, respondents also reported their frequency of exposure to each of 4 to 6 advertisements[21] on air: *Apart from this survey, how frequently have you seen these ads in the past (insert) months?* Scores for responses ranged from 0 (*never*) to 4 (*very often*). Scores across all ads were summed, resulting in a range as follows: 0—16 (first, second, and fourth follow-ups) and 0—24 (third follow-up). Overall, 6% of the sample (3%—10% by wave) reported never seeing any of the ads. A dichotomous measure from the full range of responses for the lowest 15% of scores (low or no exposure, score <4) and all others (high exposure, score>4) was created.

Models controlled for factors that influence susceptibility to tobacco use and risky behaviors.[22] A brief scale assessed sensation seeking[23] (Cronbach's α=0.74): *I would like to explore strange places; I like to do frightening things; I like new and exciting experiences, even if I have to break the rules;* and *I prefer friends who are exciting and unpredictable.* Scores for response options ranged from 1 (*disagree strongly*) to 5 (*agree strongly*). Educational plans were assessed as: *How far do you think you will go in school?* Scores for response options ranged from 1 (*I don't plan to go to school anymore*) to 8 (*graduate, medical, or law school*). School environment was measured as the mean of 3 items (α=0.79): *I feel close to people at my school; I am happy to be at my school;* and *I feel like I am a part of my school.* Scores for response options ranged from 1 (*disagree strongly*) to 5 (*agree strongly*). School performance was assessed with the item: *How well would you say you have done in school?* Scores for response options ranged from 1 (*much worse than average*) to 5 (*much better than average*). Parent communication was a mean of 2 items (α=0.69). The first was: *Thinking about the adult or adults you live with, would you say you are satisfied with the way you communicate with each other?* Scores for responses ranged from 1 (*very unsatisfied*) to 5 (*very satisfied*). The second item was: *How close do you feel to the adult or adults you live with?* Scores for responses ranged from 1 (*not close at all*) to 5 (*very close*).

Self-reported awareness of 2 other national campaigns were assessed. For truth, youth viewed a collage of ad screenshots and were asked: *Apart from this survey, how frequently have you seen these ads in the past (insert) months?* Scores for response options ranged from 0 (*never*) to 4 (*very often*). At first follow-up, the item: *In the past 3 months, have you seen or heard the following slogan or theme* Tips from Former Smokers? (*yes/no*) was assessed. For all other waves, *Tips* was assessed using a collage of screenshots and the exposure item described above. A wave-specific measure was generated as 0 or 1 (first follow-up) and 0 or 1 (never or rarely, or greater for the other waves). Media use was assessed as daily hours watching TV or movies across 4 media devices: live or streaming TV, computers/laptops/tablets, cell phones, and other personal electronics; scores for response options for each device ranged from 0 (*none*) to 4 (*>3 hours*). Responses were summed (range, 0—16).

Baseline individual characteristics included indicators for age; an indicator for female (male excluded as the reference); indicators for African-American, Hispanic, and other non-Hispanic race/ethnicity (white excluded as the reference); youth weekly

income (continuous); and the presence of a tobacco user in the household. The number of days between survey waves by individual (continuous, scaled by 30 days) and a secular time trend (categorical) were included, as well as state adult smoking prevalence from the 2013 Behavioral Risk Factor Surveillance System (1 unit increase = 1 percentage point) and 3 media market variables: median population size (in tens of thousands), median income (in tens of thousands of dollars), and media market education level (the proportion with bachelor's degree or higher). Baseline data collection occurred after campaign launch (range, 1—48 days) for 21.8% of the sample; a post-campaign indicator was included.

Statistical Analysis

Data on awareness of campaign advertisements were summarized. Attrition analyses between baseline and follow-up were conducted using chi-square significance tests. Discrete-time survival models[24,25] were estimated using logistic regression with age as the time variable. Models controlled for confounding influences, similar to other longitudinal media studies.[15,18,20,26] The risk for smoking initiation for each youth in the sample who reported never smoking at baseline was assessed as they aged during the study period. Once the event of interest (smoking initiation) occurred, the youth was dropped from subsequent time periods and the probability that a youth-initiated smoking at each age was calculated. The model included 13,970 observations from the analytic sample (N=5,103 youths). Smoking initiation over time was examined as a function of cumulative TRPs, between-wave TRPs, and self-reported frequency of exposure. TRPs were rescaled to yield ORs for the increased odds of each outcome given a unit increase of 3,500 total TRPs in each media market. This scaling unit represents the approximate size of the market-level media buy for *The Real Cost* between each survey. Analyses were conducted using unweighted data after performing a test to determine the impact of the weights on the analysis and variance.[27]

The estimated number of youths prevented from initiating smoking was calculated using the difference between the predicted risk for initiation by age for each exposure model (Table 2) and the predicted risk for initiation by age in a hypothetical scenario where exposure to the campaign is either 0 (TRPs) or low (self-reported frequency). The difference in initiation rates was then applied to the national population of nonsmoking youth at each age (2010 Census), and the resulting estimated numbers of youths potentially prevented from initiating smoking at each age were summed.

Sensitivity analyses were conducted to examine the influence of e-cigarettes and other tobacco products on smoking initiation. An additional model examined the relationship between campaign exposure and using marijuana, a risky behavior unrelated to campaign messaging, to ascertain whether campaign effects were specific to smoking behaviors or a general association between exposure and risky behaviors. Other alternate specifications were examined but not reported as they did not meaningfully alter model results: functional forms of the TRP variable (e.g., square root or parabolic), disaggregated measures of TV and online TRPs, media market-level clustering and fixed effects, and the inclusion of covariates with relatively higher missingness. All analyses were conducted with Stata, version 14.0 in 2018.

RESULTS

Table 1 displays the unweighted demographic characteristics of the analytic sample. The sample did not include 492 youths who had tried smoking at baseline, 130 youths who were missing data on smoking status, or 1,017 youths who did not complete at least 1 follow-up survey. At baseline, nonsmoking youth respondents were evenly distributed across ages 11−16 years. The sample was evenly divided by sex and was 52.7% white non-Hispanic, 28.4% Hispanic, 8.6% black non-Hispanic, and 10.3% other non-Hispanic race/ethnicities or multiracial youth. Approximately one quarter of youth reported living with a tobacco user.

An analysis of sample attrition from baseline to fourth follow-up for the full study sample found that the unweighted samples were similar across sex. As a percentage of the total sample, the fourth follow-up sample contained slightly fewer black non-Hispanic youths, fewer youths who reported living with a tobacco user, fewer experimenters, and fewer youths who were aged 15−16 years at baseline. All differences were small; the mean absolute value of difference across comparisons was 1.7% (Appendix Table 2, available online).

Youth recall of 1 or more *The Real Cost* advertisements among the analytic sample was 89.9% (first follow-up), 95.4% (second follow-up), 96.8% (third follow-up), and 95.5% (fourth follow-up). Rates of smoking initiation in the 4 follow-up surveys were 4.5%, 3.9%, 4.4%, and 5.1%, respectively.

Table 2 displays data from the survival model on the hazard of initiation for between-wave TRPs, cumulative TRPs, and self-reported campaign exposure. All 3 measures of campaign exposure were associated with decreased risk of smoking initiation, between-wave TRPs (AOR= 0.69, $p<0.01$), cumulative TRPs (AOR=0.89, $p<0.05$), and self-reported campaign exposure (AOR=0.73, $p<0.01$). For every 3,500 between-wave TRPs on air, there was an associated 31% reduction in the hazard of smoking initiation among youths. These findings were robust to alternate model specifications, including the inclusion of e-cigarette use and other tobacco product use as time-varying control variables (Appendix Table 3, available online). Models examining youth marijuana initiation found no relationship between levels of campaign exposure and initiation over time (Appendix Table 4, available online).

Figure 1 illustrates the influence of the campaign on smoking initiation estimated from the 3 exposure models. The hazard of smoking by age was plotted in the study scenario and for an alternate scenario where *The Real Cost* media does was either 0 (TRP models) or low (self-reported exposure models). The campaign was associated with an estimated 380,446 and 587,515 fewer youths initiating smoking between ages 11 and 19 years over the study period.

Table 1. Demographic Characteristics of *The Real Cost* Analytic Sample

Characteristic	Baseline n (%)
Age, years	
11	788 (15.4)
12	906 (17.8)
13	870 (17.1)
14	915 (17.9)
15	881 (17.3)
16	744 (14.6)
Sex	
Female	2,723 (53.4)
Male	2,381 (46.7)
Race/ethnicity	
White, non-Hispanic	2,690 (52.7)
Black, non-Hispanic	441 (8.6)
Hispanic	1,450 (28.4)
Other, non-Hispanic	523 (10.3)
Household tobacco use	
Yes	1,321 (25.9)
No	3,782 (74.1)
Smoking status	
Nonsusceptible nonsmoker	3,717 (72.8)
Susceptible nonsmoker	1,387 (27.2)
Census region	
Northeast	648 (12.7)
Midwest	1,008 (19.8)
South	1,774 (34.8)
West	1,674 (32.8)

Note: The analytic sample does not include *n*=1,017 youth from baseline who did not complete a follow-up survey. The sample also does not include *n*=492 youth who had already tried smoking at baseline and *n*=130 youth who we were missing data on their smoking status at either baseline or wave 1.

DISCUSSION

This nonexperimental longitudinal study is the first in a decade to demonstrate the behavioral effects of a youth-specific national media campaign using both exogenous market- and individual-level measures of exposure. Exposure to *The Real Cost* was associated with preventing approximately 380,000−587,000 U.S. youths aged 11−19 years from initiating smoking from February 2014 to November 2016. Patterns of e-cigarette use and other tobacco product use over the study period are not an explanation of the study results. Campaign exposure was associated with smoking initiation specifically,

Table 2. Results of a Discrete-Time Survival Model for Exposure and Smoking Initiation—U.S., 2014–2016

Explanatory variable[a]	Between-wave TRPs OR (95% CI)	Cumulative TRPs OR (95% CI)	Self-reported exposure OR (95% CI)
Exposure variable	**0.69**** (0.53, 0.90)	**0.89*** (0.79, 0.99)	**0.73**** (0.57, 0.92)
Age, years			
11	ref	ref	ref
12	0.82 (0.23, 2.96)	0.81 (0.22, 2.91)	0.74 (0.20, 2.71)
13	2.32 (0.71, 7.57)	2.30 (0.71, 7.50)	2.27 (0.69, 7.40)
14	**3.40*** (1.06, 10.94)	**3.37*** (1.05, 10.84)	**3.40*** (1.05, 10.96)
15	**4.03*** (1.26, 12.93)	**4.00*** (1.25, 12.82)	**4.03*** (1.25, 12.95)
16	**4.34*** (1.35, 13.91)	**4.30*** (1.34, 13.78)	**4.27*** (1.33, 13.72)
17	**4.27*** (1.32, 13.79)	**4.21*** (1.30, 13.59)	**4.23*** (1.31, 13.68)
18	**6.44**** (1.96, 21.15)	**6.33**** (1.93, 20.78)	**6.27**** (1.91, 20.64)
19	**11.39***** (3.26, 39.86)	**11.25***** (3.22, 39.34)	**11.10***** (3.17, 38.88)
Sex			
Female	ref	ref	ref
Male	1.09 (0.93, 1.29)	1.10 (0.93, 1.29)	1.09 (0.93, 1.28)
Race			
White, non-Hispanic	ref	ref	ref
Black, non-Hispanic	1.17 (0.87, 1.56)	1.16 (0.87, 1.55)	1.14 (0.85, 1.53)
Hispanic	**1.32**** (1.08, 1.61)	**1.32**** (1.09, 1.61)	**1.33**** (1.09, 1.62)
Other, non-Hispanic	0.82 (0.61, 1.11)	0.82 (0.61, 1.10)	0.82 (0.61, 1.11)
Other covariates			
Youth allowance	1.03 (1.00, 1.07)	1.03 (1.00, 1.07)	1.03 (0.99, 1.07)
Lives with a tobacco user	**1.77***** (1.50, 2.08)	**1.77***** (1.50, 2.08)	**1.74***** (1.48, 2.06)
Sensation seeking scale	**1.49***** (1.35, 1.64)	**1.48***** (1.34, 1.64)	**1.49***** (1.35, 1.65)
School environment	**0.84***** (0.77, 0.92)	**0.84***** (0.77, 0.92)	**0.84***** (0.77, 0.92)
School performance	**0.81***** (0.73, 0.89)	**0.81***** (0.73, 0.89)	**0.81***** (0.73, 0.89)
School plans	**0.92*** (0.85, 0.99)	**0.92*** (0.85, 0.99)	**0.92*** (0.85, 1.00)
Parental communication	**0.88**** (0.80, 0.97)	**0.88**** (0.80, 0.97)	**0.88**** (0.80, 0.97)
Media use	**1.03**** (1.01, 1.05)	**1.03**** (1.01, 1.05)	**1.03**** (1.01, 1.05)
Wave			
1	ref	ref	ref
2	**0.66***** (0.52, 0.84)	**0.72*** (0.55, 0.94)	**0.62***** (0.49, 0.78)
3	**0.51***** (0.39, 0.67)	**0.65*** (0.45, 0.93)	**0.50***** (0.38, 0.66)
4	**0.60***** (0.46, 0.80)	0.82 (0.51, 1.31)	**0.54***** (0.41, 0.72)
Time between waves	**1.13**** (1.04, 1.23)	**1.09*** (1.01, 1.18)	**1.09*** (1.01, 1.18)

Note: Boldface indicates statistical significance (*$p<0.05$; **$p<0.01$; ***$p<0.001$).
[a]Additional control variables include average market-level family income, average market-level high school completion rates, market population, 2013 Behavioral Risk Factor Surveillance System state smoking prevalence, measures of self-reported exposure to the *Tips From Former Smokers* and the Truth Initiative's truth® campaigns, an indicator for whether the youth's baseline interview was conducted after the launch of *The Real Cost.*
TRP, target rating point.

rather than a general pattern of associations between risk behaviors and campaign media delivery.

These data add to the body of research demonstrating that state and national tobacco education campaigns are effective. This study supports the conclusions of other effective campaigns,[17,18] specifically that high levels of extended advertising are required for media campaigns to achieve sustainable population changes in smoking behavior. Demonstrating the effects of digital and TV media on population-level behavior for youth requires longitudinal studies with sufficient sample sizes, which

can be costly. However, the findings add uniquely strong evidence to the knowledge base for the study of public health campaigns in real-world settings.

Limitations

This study has several limitations. First, sample attrition over time may have resulted in biases. Overall, there were few differences between youths in the completed sample and those missing at follow-up. However, youths in the sample who had experimented with cigarettes at baseline were more likely to drop out at follow-up; thus,
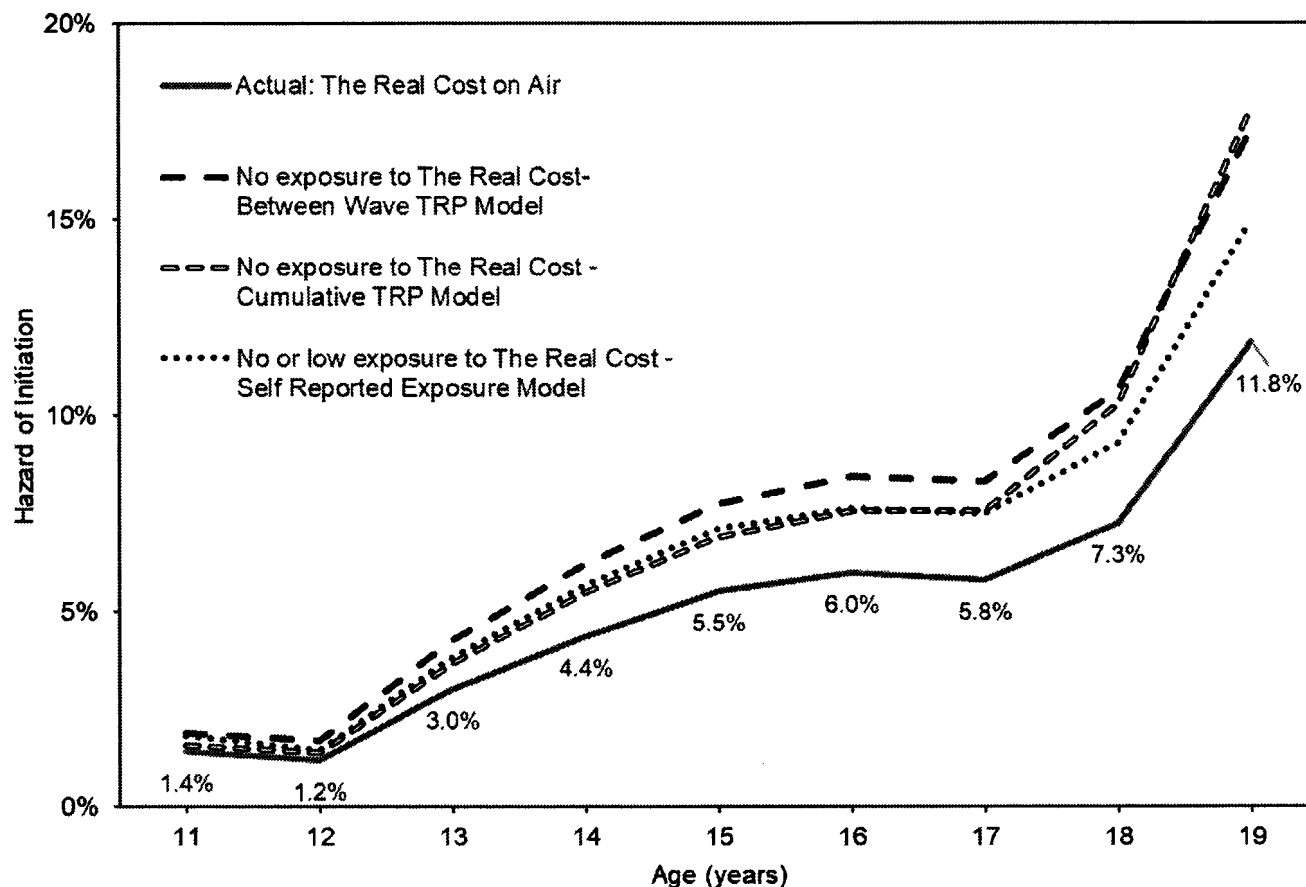
Figure 1. Estimated smoking initiation risk among youths aged 11−19 years, by age—U.S., 2014−2016.
TRP, target rating point.

there may be bias in the analytic sample because of reduced completion rates among youths who experimented with cigarettes between study waves. Second, although the model controls for youths' exposure to other tobacco-related media campaigns, this might not fully account for the independent or synergistic effects of the other campaigns. Third, owing to the current measurement limitations in digital advertising, digital TRPs in the study did not vary greatly, so differentiating the independent effect of digital advertising was not possible. Fourth, only smoking initiation was examined in this study; data on progression to established or daily smoking were limited by sample size. Relatedly, this campaign examines initiation over a 2-year period, and longer studies are required to determine whether the campaign effectively delayed smoking initiation or led to sustained abstinence among this cohort.

CONCLUSIONS

Youths are at their highest lifetime risk for smoking initiation during adolescence[22] and young adulthood. Media campaigns like *The Real Cost*, in combination with other comprehensive tobacco control efforts, contribute to reductions in smoking uptake among youths nationwide, reducing future rates of cardiovascular disease, respiratory disease, cancer, and other deadly tobacco-related diseases.[9,22] A tobacco-free cohort today would reduce future smoking-attributable mortality, healthcare costs, and lost workplace productivity.[28−30] Continued efforts to prevent youths from becoming addicted to tobacco products will reduce greatly the public health burden of cigarette smoking in the U.S.

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SUPPLEMENTAL MATERIAL

Supplemental materials associated with this article can be found in the online version at https://doi.org/10.1016/j.amepre.2019.06.011.

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RESEARCH ARTICLE

Graphic Warning Labels Elicit Affective and Thoughtful Responses from Smokers: Results of a Randomized Clinical Trial

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Abstract

Objective

Observational research suggests that placing graphic images on cigarette warning labels can reduce smoking rates, but field studies lack experimental control. Our primary objective was to determine the psychological processes set in motion by naturalistic exposure to graphic vs. text-only warnings in a randomized clinical trial involving exposure to modified cigarette packs over a 4-week period. Theories of graphic-warning impact were tested by examining affect toward smoking, credibility of warning information, risk perceptions, quit intentions, warning label memory, and smoking risk knowledge.

Methods

Adults who smoked between 5 and 40 cigarettes daily (N = 293; mean age = 33.7), did not have a contra-indicated medical condition, and did not intend to quit were recruited from Philadelphia, PA and Columbus, OH. Smokers were randomly assigned to receive their own brand of cigarettes for four weeks in one of three warning conditions: text only, graphic images plus text, or graphic images with elaborated text.

Results

Data from 244 participants who completed the trial were analyzed in structural-equation models. The presence of graphic images (compared to text-only) caused more negative affect toward smoking, a process that indirectly influenced risk perceptions and quit intentions (e.g., image->negative affect->risk perception->quit intention). Negative affect from graphic images also enhanced warning credibility including through increased scrutiny of the warnings, a process that also indirectly affected risk perceptions and quit intentions (e.g., image->negative affect->risk scrutiny->warning credibility->risk perception->quit

intention). Unexpectedly, elaborated text reduced warning credibility. Finally, graphic warnings increased warning-information recall and indirectly increased smoking-risk knowledge at the end of the trial and one month later.

Conclusions

In the first naturalistic clinical trial conducted, graphic warning labels are more effective than text-only warnings in encouraging smokers to consider quitting and in educating them about smoking's risks. Negative affective reactions to smoking, thinking about risks, and perceptions of credibility are mediators of their impact.

Trial Registration

Clinicaltrials.gov NCT01782053

Introduction

Cigarette smoking causes about 480,000 deaths in the United States (US) each year [1]. In attempts to reduce smoking-related mortality, graphic warning labels on cigarette packaging are now required in 77 countries [2] and were mandated in the US in 2009. However, the DC Circuit Court, a US judicial body that has the authority to invalidate laws it deems unconstitutional, blocked the graphic warning requirement, concluding in part that the images proposed by the Food and Drug Administration (FDA) were unconstitutional and "unabashed attempts to evoke emotion. . .and browbeat consumers into quitting" [3]. An earlier 2011 memorandum predicted this later ruling: "the emotional response they were crafted to induce is . . . an objective wholly apart from disseminating purely factual and uncontroversial information" [4]. The aim of the present paper is to examine this statement in light of psychological theory about the effects of emotion on risk perception and informed decision making (from here on, we use the terms emotion, feelings, and affect interchangeably). In particular, we consider the negative affect elicited by graphic warnings to be an important source of health information and driver of cognitive processes critical to informed decisions among smokers. This paper presents data from a randomized clinical trial that is consistent with this notion.

Experimental research aligns with the court's assertion that graphic warning labels evoke more negative emotion than text-only labels; these negative feelings also generalize to smoking-related cues (e.g., images of cigarettes) [5, 6, 7]. Despite the Court's assertion, such emotional reactions to danger have been shown critical to the quick perception and reaction to risk that has been necessary for avoiding health and other hazards across human evolutionary history [8]. These emotions can influence behavior directly, motivating us to engage in pleasant, rewarding behaviors and avoid unpleasant, potentially dangerous activities [8]. Affect also acts as an important source of information, informing us whether the water is safe to drink or it's okay to enter a dark alley (via an Affect Heuristic). In other words, affective responses can serve as simple cues or heuristics enabling people to skirt hazards quickly and efficiently [8, 9]. These are important ways that graphic warning labels may assist smokers, most of whom want to quit and/or wish they had never started smoking [10].

Affect, thus, serves multiple functions in risk perception and decision processes [11, 12]. This line of research also points towards affect influencing perceptions of health risks by motivating people to think more carefully about the risks [11]. Peters [12], for example, proposed

that affect plays a role as a spotlight in a two-step process. First, enhanced affective feelings (e.g., those aroused by graphic warnings in the present study) encourage the decision maker to focus on new information consistent with those feelings (in this case, the risk information). Second, the new information (rather than the initial feelings) is used to guide further judgments and decisions. Thus, we expect affect-laden graphic warnings to highlight health-risk information, promote greater processing and acceptance of it, and, in turn, increase smoking risk perceptions and quit considerations. Consistent with this, graphic warnings have been shown to elicit increased evaluations of warning credibility that may encourage quitting [13]. Such cognitions are important because evaluations formed from carefully thinking about information last even longer [14] and are even more predictive of behavior [14, 15, 16]. Understanding the processes through which affect influences risk perceptions and quit intentions among smokers represents the primary objective of the current research.

We further predicted that smokers given graphic warnings would remember more health information from them than those given text-only warnings. Graphic images contain more detailed information than is available in brief textual warnings. For example, showing an image of advanced oral cancer on the lip of a person who also has diseased teeth and gums says more to the smoker than simply saying "cigarettes cause cancer." In addition, our hypothesis has a basis in past research showing that affective arousal increases memory for associated information [17, 18, 19]. Consistent with both lines of thought, survey research shows that smokers in countries with graphic warning labels can identify more smoking risks than smokers in countries with text-only warnings [20, 21]. Improving our understanding of how graphic warning labels influence smokers' risk knowledge represents an important secondary objective of this trial.

In addition to images, another label component that can influence the perceived credibility of warnings is the addition of text that elaborates on the risk information in the warnings. Emery et al. [13] found that elaborated risk information (similar to that used in Canada) increased perceived warning credibility, which decreased smoking desires. Because smokers do not appreciate the cumulative risks associated with smoking [22], we designed elaborative text that emphasized the additional risk that each cigarette posed to the smoker. Whether messages emphasizing cumulative risks would be compelling to regular smokers (and especially smokers not intending to quit) was not clear. We anticipated that, consistent with past research showing the superiority of elaborated text [13], such messages would enhance warning credibility, an effect that would indirectly influence risk perceptions and quit intentions.

A recent meta-analysis of 37 laboratory-based experimental studies concluded that one-time exposure to graphic vs. text-only warning labels leads to heightened quit intentions among smokers [23]. However, a naturalistic experiment is a key addition to this literature because, compared to single-exposure studies, the experience of a pack-a-day smoker is likely much different, with 600 potential exposures to graphic warnings on cigarette packs per month. It seems unlikely that the first label response would be the same as the 599th. In particular, the effects of graphic images on negative affect towards smoking may be short-lived as smokers could avoid the warnings or habituate to them over time [24, 25]. If true, graphic warnings will lose efficacy over time. However, we anticipated that their emotional impact would change smokers' feelings about their habit and motivate greater processing of risk information [11], leaving the smoker with enhanced knowledge and heightened risk perceptions even after the immediate emotions waned. The present study, to our knowledge, is the first to randomly assign smokers to receive graphic vs. text-only warnings on their cigarette packs over a relatively long duration (four weeks).

We conducted a randomized clinical trial to experimentally study smokers in a naturalistic setting in order to test causal claims based on longer term exposures than past experiments.

We compared three conditions: text-only using the nine Congressionally-mandated messages; mandated text plus FDA-proposed images [26]; and elaborated text combined with the mandated messages and proposed images. Consistent with past research [6, 13, 27], we tested our hypotheses using mediated models with affect, risk scrutiny, perceived credibility, and label memory as mediators of warning label effects on risk perception, quit intentions, and risk knowledge. We tested the following hypotheses:

Hypothesis 1a (H1a): Graphic warning labels will cause greater negative affect toward smoking among adult smokers, an effect that will indirectly motivate action by increasing quit intentions and serve as information about the dangers of smoking by increasing risk perceptions.

Hypothesis 1b (H1b): The negative affect created by graphic images will enhance the credibility of the warnings by increasing scrutiny of the warning information, an effect that will indirectly increase risk perceptions and quit intentions.

Hypothesis 2 (H2): Elaborative text will increase the credibility of the warning message, an effect that will also indirectly increase risk perceptions and quit intentions.

Hypothesis 3 (H3). Graphic warning labels will enhance recall of warning information, an effect that will be explained in part by negative affect elicited by the graphic labels. This greater label memory will indirectly increase participants' knowledge of smoking risks at the end of the trial and at post-trial follow-up.

Materials and Methods

The protocol for this trial and CONSORT checklist are available as supplemental information; see S1 Protocol and S1 Checklist. The trial was registered at Clinicaltrials.gov with the reference NCT01782053.

Ethics statement

This study was conducted in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. The investigation was approved by the University of Pennsylvania Institutional Review Board (IRB), which served as the IRB of record for this trial. Prior to participation, all participants provided written consent by signing an IRB approved document indicating that they understood the trial protocol and agreed to participate. In addition to receiving cigarettes in experimental packaging at no cost, participants were paid up to $235 for completing the full trial and adhering to all elements of the protocol. No adverse events occurred during the trial.

Participants and procedure

Sample size was determined by power analysis using G*Power [28], see S1 Protocol. Our primary outcome of interest in this trial was quit intentions. Based on past experimental investigations exploring the impact of graphic warning labels on quit intentions [6], we predicted an effect size of .35. Sample size estimates were calculated for 80% power and a two-tailed alpha of .05. After collapsing from 5 to 3 conditions as described below, we estimated that we would need 260 participants to identify a direct effect of graphic vs text-only warnings condition on quit intentions using unadjusted analysis of variance (ANOVA).

Study participants were 293 adult smokers (M_{Age} = 33.68, SD = 11.56, 45% female) recruited through fliers and ads placed on social media websites in Columbus, OH (N = 145) and Philadelphia, PA (N = 148). Recruitment was conducted from January 2013 and February 2014. All follow-up was completed by April, 2014. An initial phone screening was used to exclude individuals who smoked <5 cigarettes or >two packs per day, reported being *likely* or *very likely* to quit smoking in the next 30 days, had a contra-indicated medical condition (e.g., pregnancy),

were currently being treated for a psychiatric condition or who reported a history of substance abuse. Complete inclusion and exclusion criteria can be found in S1 Protocol. Most participants identified themselves as being White (62%), 31% as Black, and 5% as more than one race. Remaining participants identified as American Indian ($n = 3$), Asian ($n = 2$) or "other" ($n = 1$). Participants reported smoking an average of 16.99 ($SD = 7.87$) cigarettes per day, and they reported having been a smoker for 17.14 ($SD = 12.04$) years. Nicotine dependence was assessed by the Fagerström Test of Nicotine Dependence [29]. The mean score was 4.37 ($SD = 1.78$) indicating moderate dependence, which was biochemically supported by breath carbon monoxide (CO) sample at intake ($M = 17.93$ ppm, $SD = 10.63$)[29].

Participants were stratified on the basis of gender, amount smoked, and quit intentions, then randomly assigned to conditions by research assistants. The randomization scheme was generated by an individual who did not interact with participants. The protocol was open label; thus no attempts at blinding were made for experimenters or participants. No differences existed between conditions on demographic characteristics or baseline smoking behaviors at randomization (see S1 Table). Depending on their assigned experimental condition, participants received their own brand of cigarettes with packages modified by text-only warning labels, graphic warning labels, or graphic warning labels that included elaborated text. Early participants (n = 117) were randomized to one of 5 conditions at a 1:1:1:1:1 ratio. The presence vs. absence of a quitline number was manipulated in conditions with images. No participant ever called the quitline. Thus, the quitline number was dropped and participants who had been exposed the quitline number were analyzed as members of the parent condition (graphic or elaborated). This change in the protocol, which was approved by the funding agencies, enabled us to recalculate the power analysis and recruit fewer participants (see S1 Protocol). For the remainder of the study, participants were randomly assigned to one of the three experimental conditions. The randomization scheme was adjusted to increase the likelihood that later participants would be included in the text-only condition, resulting in a 1:1:1 ratio across conditions for the study.

Participants returned to the lab each week to receive additional cigarettes and respond to surveys about their experiences with the new packaging. Participants returned any unused cigarettes from the prior week at each appointment. To reduce possible demand characteristics from exposure to cigarette packages, they completed all dependent measures at a private computer work station with no cigarette packages within sight. At the same time, a research assistant prepared cigarettes for the next week in an adjoining room. Retention was high at the end of the trial (84.6%). At that time, participants completed key dependent measures on a computer. About one month later, experimenters were able to contact most participants (60.8%) by phone for a voluntary follow-up survey, Fig 1. Further details of the experimental protocol can be found in S1 Protocol.

Independent variable

Graphic Warning Manipulation. Each week, participants were given a one-week supply of their preferred brand of cigarettes. In the first week, participants were given cigarettes in non-modified packages based on self-reported amount smoked. In subsequent weeks, participants were given cigarettes in modified packages based on the amount they smoked the previous week as measured by cigarette filters returned at each lab visit [30] (see S1 Protocol for additional details). For four weeks, warning labels appropriate to their randomized experimental condition were affixed to each pack. All participants received the same nine basic text messages (e.g., "Cigarettes cause fatal lung disease.") mandated by the Family Smoking Prevention and Control Act. Participants in the text-only condition received packages of cigarettes modified with only this basic text information, which was placed on the side of each package (see
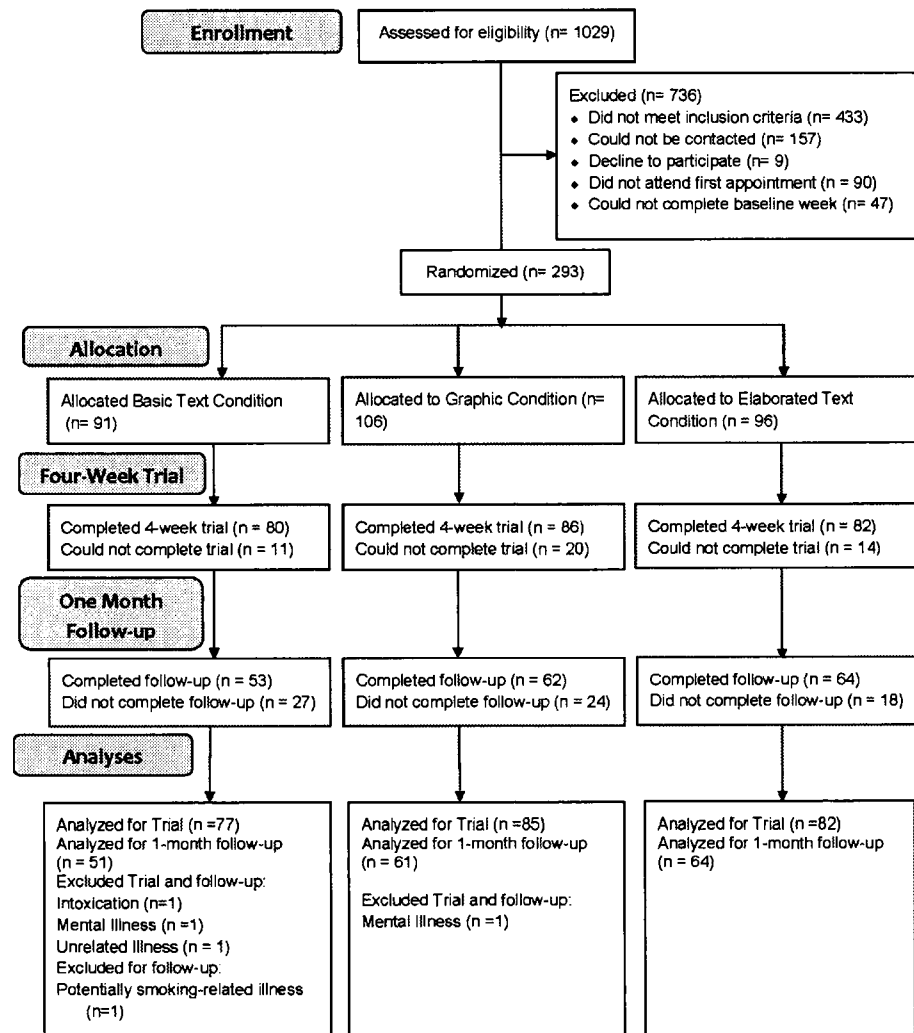
Enrollment

Assessed for eligibility (n= 1029)

Excluded (n= 736)
- Did not meet inclusion criteria (n= 433)
- Could not be contacted (n= 157)
- Decline to participate (n= 9)
- Did not attend first appointment (n = 90)
- Could not complete baseline week (n= 47)

Randomized (n= 293)

Allocation

Allocated Basic Text Condition (n= 91)

Allocated to Graphic Condition (n= 106)

Allocated to Elaborated Text Condition (n = 96)

Four-Week Trial

Completed 4-week trial (n = 80)
Could not complete trial (n = 11)

Completed 4-week trial (n = 86)
Could not complete trial (n = 20)

Completed 4-week trial (n = 82)
Could not complete trial (n = 14)

One Month Follow-up

Completed follow-up (n = 53)
Did not complete follow-up (n = 27)

Completed follow-up (n = 62)
Did not complete follow-up (n = 24)

Completed follow-up (n = 64)
Did not complete follow-up (n = 18)

Analyses

Analyzed for Trial (n =77)
Analyzed for 1-month follow-up (n = 51)
Excluded Trial and follow-up:
Intoxication (n=1)
Mental Illness (n =1)
Unrelated Illness (n = 1)
Excluded for follow-up:
Potentially smoking-related illness (n=1)

Analyzed for Trial (n =85)
Analyzed for 1-month follow-up (n = 61)

Excluded Trial and follow-up:
Mental Illness (n =1)

Analyzed for Trial (n =82)
Analyzed for 1-month follow-up (n = 64)

Fig 1. Participant Retention Diagram. Participant recruitment and retention over the course of the trial.

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Fig 2 for examples in all three conditions; for full materials see S1–S3 Figs). Participants in the graphic image condition received the same basic text plus related images; these warnings covered approximately 50% of the front and back of each pack (placed so as not to cover brand information). These graphic labels featured the nine images proposed by FDA for inclusion on US cigarette packs [26]. Participants in the elaborated text condition received packs with warnings covering the same package space; these labels included the same text and images plus additional text describing how every cigarette entails risk (e.g., "Every cigarette you smoke increases your risk of crippling, often fatal, lung diseases such as emphysema."). Participants were exposed to each label in their condition in approximately equal proportions over the experimental period.

Dependent measures

Smoking behavior. To monitor smoking behavior over the course of the trial, participants were required to return their used cigarette filters to the lab each week [30]. Participants were
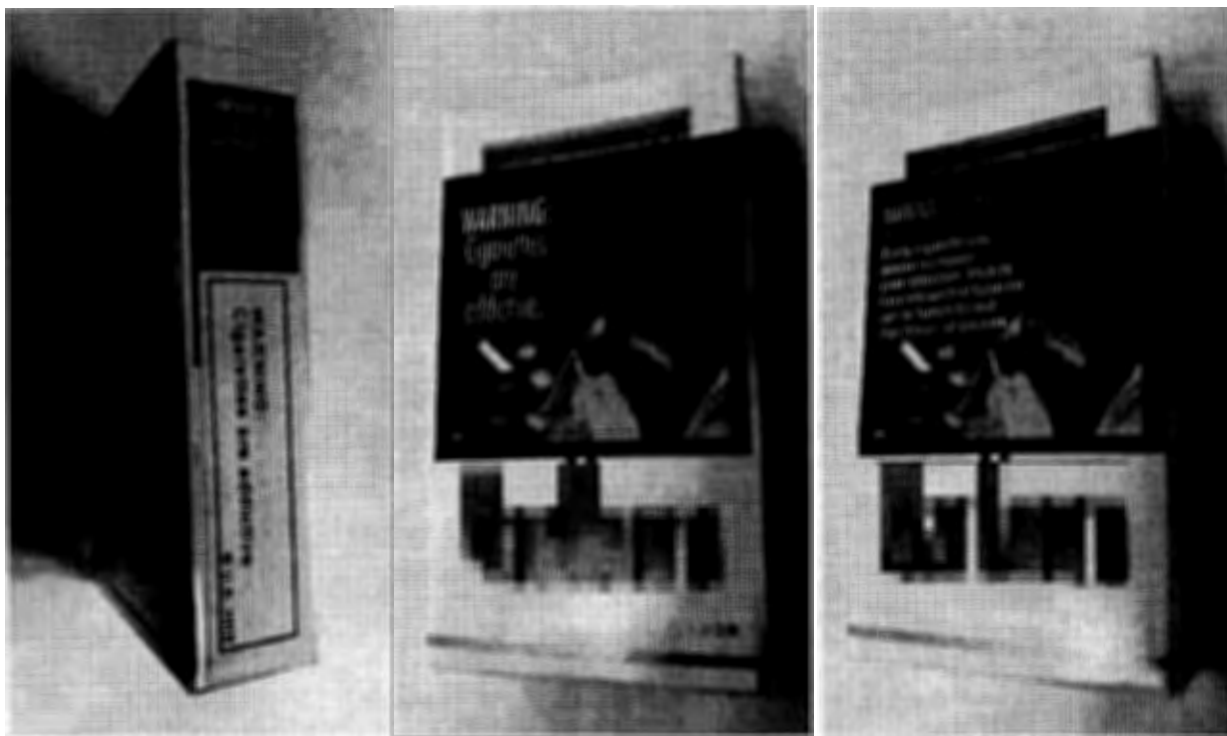
Fig 2. Placement of Experimental Warning Labels. Basic text warnings (left) were placed on the side of cigarettes packages. Graphic warning labels (center) covered approximately 50% of the front of cigarette packages and paired images with basic text statements. Elaborated text warning labels (right) also featured graphic images, but included descriptive text which explained the warning in more detail.

provided with a resealable plastic pouch for each day between laboratory sessions. Returned filters were counted to measure smoking behavior. To estimate smoking behavior before packaging was manipulated, the number of filters returned each day during the baseline period was averaged. To estimate smoking behavior during the trial, the number of filters returned each day during the modified warning labels period was averaged.

Negative affect. During their third lab visit, after using cigarettes in modified packaging for one week, participants were asked to indicate the extent to which the cigarette packaging affected their feelings about smoking ("Did the packaging change how you feel about smoking?" 1 = the packaging made me feel much worse about smoking; 4 = the packaging had no effect; 7 = the packaging made me feel much better about smoking). This item was adapted from past research [7] and reverse coded, so that higher scores indicated more negative affect.

Risk scrutiny. Scrutiny of risk information was also assessed during the third lab visit using a measure adapted from past research on warning label scrutiny [31]. Participants were asked "In the past week, have you read or looked closely at the information on your cigarette packs?" and answered on a 5-point scale (1 = *not at all* to 5 = *extremely often*).

Warning credibility. Perceptions of warning credibility were assessed after four weeks of exposure to the experimental warning labels, during the sixth and final lab visit. After completing all other dependent measures, participants viewed each warning label that had been on their cigarette packages during the study and responded to "Do you believe that what this information says is true?" (1 = *not at all* to 7 = *completely*). This measure was adapted from past research on perceptions of cigarette warning label credibility [13] and used to construct an index of perceived warning credibility by averaging ratings across labels (Cronbach's α = .92).

Risk perceptions. Subjective perceptions of smoking illness risk were assessed on three 7-point scales adapted from past research on smoking risk perceptions [32, 33] during the final lab visit. Comparative risk perceptions were assessed with "Compared to the average person your age, gender, and race, how would you rate your chances of getting a life-threatening illness because of smoking?" (1 = *much lower* to 7 = *much higher*). Absolute risk perceptions were assessed with two items: "If I continue to smoke, I think my chances of getting a life-threatening illness are" (1 = *almost zero to 7* = *almost certain*) and "If I continue to smoke, I would feel very vulnerable to dying at a younger age than I would otherwise" (1 = *strongly disagree to 7* = *strongly agree*).

Quit intentions. During their final lab visit, participants responded to three items relevant to quit intentions. These items included a contemplation ladder [34], which asked them to choose the number that indicates their current thinking about smoking on a 9-point scale (1 = taking action to quit [e.g., cutting down, enrolling in a program]; 3 = starting to think about how to change my smoking patterns; 5 = think I should quit but not quite ready; 7 = think I need to consider quitting someday; and 9 = no thought of quitting). This item was reverse-scored. Participants also responded to two 4-point scale items adapted from past research [35], which asked "How likely do you think it is that you will try to quit smoking within the next 30 days?" (1 = *very unlikely* to 4 = *very likely*) and "How much do you want to quit smoking?" (1 = *not at all* to 4 = *a lot*).

Label memory. Consistent with procedures used in past research to investigate memory for emotional events, participants were asked to recall the warning labels during their final laboratory session in the trial [6, 36]. An open-ended item asked "Please think about the packaging of the cigarettes we have given you over the past few weeks. Please try to recall what the information on the packages stated and write it in below." Participants were given nine text boxes and no time limits to list as much information as they could recall. Four independent coders evaluated responses for evidence of the presence of memory for the components of each label (basic text/images/ elaborated text). Although lung cancer and throat cancer were not mentioned explicitly on the warning labels, participants often inferred these illnesses from information on the labels. Thus, any mention of lung or throat cancer was included as memory for label content, but was not classified as memory for any specific label element. This resulted in a total possible score of 29. Inter-rater reliability was established for memory of each label component (mean Krippendorff's α = .95) and the number of components recalled (Krippendorff's α = .96).

Smoking risk knowledge. Participants' knowledge of smoking-related illnesses also was measured through a free response task at the end of the trial. Some researchers believe that free response measures are better indicators of smoking risk knowledge than responses to closed ended questions [37]. Participants responded to the item "What are some diseases you've heard about that can be related to tobacco use?" Participants were given a large text box in which to enter as many diseases as they could think of. Two independent coders examined these responses and coded for any mention of 29 different smoking-related health risks. Responses were coded for widely known smoking-related illnesses (e.g., lung cancer; heart disease) and less widely known risks (e.g., breast cancer; joint problems). Inter-rater reliability was high (Krippendorff's α = 1.00). Risk knowledge was calculated by summing the number of smoking-related illnesses mentioned (possible range = 0–29).

During a telephone follow-up one month later, participants were asked again to verbally list as many smoking-related diseases as they could. These responses were recorded by research assistants and again coded by two independent coders for the presence of 29 different smoking-related illnesses. Inter-rater reliability was high (Krippendorff's α = 1.00).

Analysis Strategy. Prior to our primary analyses, one-way analysis of variance (ANOVA) and chi-square (χ^2) tests were used to investigate the possibility that participant demographic characteristics or baseline smoking behaviors might differ as a function of experimental condition at randomization and in the data we analyzed. We also used unadjusted one-way ANOVAs to investigate the possibility that participant exposure to the warning information might have differed as a function of experimental condition and that warning label exposure may have had direct effects on key outcome variables.

Consistent with an intention to treat analysis strategy, available data for participants who completed the trial were analyzed as if they had complied with the intervention condition to which they were randomly assigned, regardless of compliance with the experimental protocol. All analyses were conducted after the end of the trial and follow-up data collection. To test hypotheses about the indirect (mediated) effects of exposure to graphic warning labels, we used structural equation modeling (SEM). Analyses were conducted using MPlus Version 7 [38]. We created two orthogonal contrast-coded predictors to represent the effects of the two warning conditions. One predictor contrasted the two graphic conditions (coded as 1) versus text-only warnings (coded as -2). The other contrasted the elaborated text condition (coded as 1) versus the graphic-only condition (coded as -1), with the text-only condition coded as 0. We used these contrast codes to fit models based on our theoretically derived predictions about the indirect effects of graphic warning labels on risk perceptions, quit intentions, and smoking risk knowledge. In the structural equation models, a pairwise present approach was taken to handling missing data for participants who completed the trial. This approach uses all available data about variable relationships in estimating model parameters.

To assess the possibility that non-normal distribution could influence results, all analyses were first conducted using maximum likelihood estimation with robust standard errors, an approach to structural equation modeling that is robust to non-normally distributed data [39]. Modification indices were used to identify plausible paths not predicted by our theoretical framework. Satorra-Bentler scaled χ^2 comparison tests were computed to compare nested models [40]. Models which evidenced acceptable fit were recalculated using bootstrap resampling. We used several different indices to determine the fit of each structural equation model including the normed χ^2 and the relative χ^2 [41]. A non-significant χ^2 and a relative χ^2 of less than 2 indicate good model fit [41]. We also report the root mean squared error of approximation (RMSEA). RMSEA values below .05 are considered to indicate that the model fits the data well [42]. Finally, we report the Comparative Fit Index (CFI), and the Tucker-Lewis Index (TLI). CFI and TLI values above .95 are considered indicators of good model fit [42]. For the purpose of comparing non-nested models, we also report the Akaike information criterion (AIC) and Bayesian information criterion (BIC). The significance of indirect (mediated) effects was assessed by using bootstrap re-sampling procedures, which used 5,000 random samples drawn from the existing data with replacement to generate bias-corrected confidence intervals for each indirect effect [43]. Confidence intervals which do not contain zero indicate a significant indirect effect. Bootstrap resampling is well suited to estimating indirect effects in multiple mediator models because confidence intervals are based on the sampling distribution of the indirect effect rather than an assumed normal sampling distribution [44, 45].

To address the possibility that differential attrition based on demographic characteristics or smoking behavior might bias our results, we used logistic regressions and χ^2 tests to compare the characteristics of participants randomized to experimental conditions who did vs. did not complete the trial. Individual differences that were related to attrition were used to create imputation models from which we imputed missing data and retested each of our hypotheses. To do so, we created ten data sets using multiple imputation with chained equations (MICE) in

Stata version 12 [46]. Structural equation models were then calculated from the imputed data sets using the MPlus multiple imputation analysis procedures.

Finally, to further assess the validity of our theoretically derived model described in hypotheses 1 and 2, we also tested the fit of the data to two plausible alternative models and report their fit statistics. We compared the fit of the data to these models to the fit of the data in our hypothesized model using the AIC and BIC.

Results

In our primary analyses, participants who did not complete the week six appointment were excluded from analyses (n = 45). Retention did not differ as a function of experimental condition. Four additional participants were excluded from analyses (two were hospitalized for mental illness during the trial, one was diagnosed with a possible smoking-related illness during the trial, and one reported intoxication during lab sessions), leaving 244 participants at week 6. Follow-up data were excluded for one additional participant who was diagnosed with a possible smoking related illness after completing the trial. Demographics did not differ by experimental condition at random assignment (see S1 Table) or at the end of the trial, Table 1. Additionally, previous research does not identify demographic differences as moderators of the impact of graphic warnings labels [47]. Therefore, reported one-way ANOVAs do not control for demographic variables. All reported structural equation models controlled for the demographic variables used in stratified randomization. Specifically, all reported structural equation models control for gender (female vs. male), baseline smoking heaviness (less vs. more than 20 cigarettes per day), and baseline quit intentions (1 "very unlikely" vs. 2–4 "very likely").

Participant smoking behavior did not differ significantly by experimental condition during the baseline period, $F(2, 241) = .62, p = .538$, or during the trial period, $F(2, 241) = .79, p = .454$, Table 2. On average, participants were exposed to the warning labels over 15.7 times per day across conditions during the trial. A paired samples t-test comparing the rates of smoking at baseline and during the trial revealed a trend indicative of a slight increase in smoking behavior after the baseline period $t(243) = 1.86, p = .064$, which may be the result of participants acclimating to receiving experimental cigarettes at no cost.

Due to a computer error, 30-day quit intentions were not recorded for 22 participants who completed the trial. Because 30-day quit intentions were also measured at week 5 and the week 5 and week 6 responses were highly correlated ($r = .76, p < .001$), we carried forward week 5 quit intention responses to week 6 for participants missing this item only. Model fit, path coefficients, and indirect effects were comparable when these participants were excluded list-wise.

One-way ANOVAs revealed that the graphic warning conditions (compared to text-only) increased negative affect toward smoking, scrutiny of the risks, and label memory. The graphic-only condition increased warning credibility relative to the other two conditions. There were no significant differences between conditions in risk perceptions, quit intentions, or risk knowledge, Table 3.

Hypotheses 1 and 2

We proposed that graphic warning labels would influence risk perceptions, and quit intentions in turn, through multiple affective paths. To ensure that risk perceptions and quit intentions were sufficiently distinct constructs, we compared measurement models with one vs. two factors. The single factor model did not fit the data well, as evidenced by a highly significant χ^2 (χ^2 [9] = 90.50, $p < .001$), high RMSEA (.193), and low CFI (.861) and TLI (.769) values. A two-factor model offered a better fit, ($\chi^2[8] = 11.93, p = .155$; RMSEA = .045, CFI = .99; TLI = .99). A $\chi2$ difference test for nested models revealed that the two-factor solution fit the data better

Table 1. Demographics of included participants by experimental condition at week 6.

	Text-only (N = 77)	Graphic Images (N = 85)	Graphic Images and Elaborated Text (N = 82)	Test Statistic, p-value
Age				
	32.78 (11.57)	34.98 (11.59)	35.12 (11.96)	$F(2, 241) = .99, p = .37$
Gender				
Male	40	47	46	$\chi^2 (2) = .35, p = .84$
Female	37	37	36	
Other	0	1	0	
Race				
White	45	53	48	$\chi^2 (4) = 3.39, p = .49$
Black	26	24	31	
Asian	1	1	0	
American Indian	2	1	0	
More than one	2	5	3	
Other	1	1	0	
Ethnicity				
Hispanic	2	3	3	$\chi^2 (2) = .17, p = .92$
Non-Hispanic	75	82	79	
Education				
Some high school, no degree	6	6	6	$\chi^2 (8) = 6.31, p = .61$
High school degree or GED	21	16	24	
Some college, no degree	29	43	31	
Associate's Degree	9	7	5	
Bachelor's Degree	12	11	12	
Master's Degree or higher	0	1	2	
Self-report Cigarettes Smoked Daily				
	15.79 (6.94)	16.82 (7.82)	16.40 (7.81)	$F(2, 241) = .38, p = .69$
Years of Smoking				
	16.52 (11.81)	18.15(12.60)	17.88(12.15)	$F(2, 241) = .41, p = .67$
Fagerström Test of Nicotine Dependence				
	4.51 (1.77)	4.27 (1.94)	4.32 (1.85)	$F(2, 241) = .36, p = .70$
Breath Carbon Monoxide (CO)				
	17.01 (10.13)	19.45 (13.02)	18.99 (9.68)	$F(2, 241) = 1.09, p = .34$

Due to a low number of participants in certain groups, some categories were combined in χ^2 tests for demographic differences after random assignment. The participant who indicated their gender as "other" was excluded from the χ^2 test for gender. Participants who indicated their race as Asian, American Indian, More than one race, or Other, were combined to form a single "other" category. Finally, participants with a Master's degree or higher were combined with participants who held a Bachelor's degree to form a single high-education category.

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than the one-factor model ($\chi^2_{\text{Diff}} = 78.57, p < .001$). Thus, a two factor measurement model was appropriate for tests of Hypotheses 1 and 2. We predicted that the presence of graphic images would increase negative affect toward smoking, which would increase risk perceptions and quit intentions directly and indirectly by encouraging smokers to think about and form favorable evaluations of the risk information warnings provided. A model testing these

Table 2. Average smoking behavior by experimental condition at baseline and during the trial.

	Text-only Mean (SD)	Graphic Images Mean (SD)	Graphic Images and Elaborated Text Mean (SD)	Omnibus Effect Size η_p^2
Filters returned during baseline	14.76 (6.41)	16.01 (7.22)	15.42 (7.63)	.01
[CI 95]	[13.95, 15.56]	[15.1, 16.91]	[14.46, 16.38]	
Filters returned during the trial	14.85 (6.93)	16.29 (7.55)	15.95 (8.11)	.01
[CI 95]	[13.97, 15.72]	[15.34, 17.24]	[14.93, 16.97]	

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predictions using maximum likelihood estimation with robust standard errors fit the data well ($\chi^2[59] = 65.59$, $p = .259$, relative $\chi^2 = 1.11$, RMSEA = .02 [CI 90: .00 to .05], CFI = .99, TLI = .99). However, modification indices suggested that including a path from negative affect to perceived credibility would improve model fit. A model with this path was estimated using maximum likelihood estimation with robust standard errors and also fit the data well ($\chi^2[58] = 61.52$, $p = .351$, relative $\chi^2 = 1.06$, RMSEA = .02 [CI 90: .00 to .04], CFI = 1.00, TLI = .99). A Satorra-Bentler scaled χ^2 difference test revealed that the alternative model provided a marginally better fit to the data than the hypothesized model, $\chi^2[1] = 3.70$, $p = .056$). Therefore, this path was retained in our final model, which was retested using bootstrap resampling to calculate confidence intervals for indirect effects. Modification indices did not suggest any additional paths to be added or removed from the model.

The final model testing Hypotheses 1 and 2 is depicted in Fig 3. The recalculated model with bootstrap resampling also fit the data well, as evidenced by a non-significant χ^2 ($\chi^2[58] = 62.94$, $p = .306$), a relative χ^2 of less than 2 (1.09), a low RMSEA (.02, CI 90: .00, .05), and high CFI and TLI values (.99 and .99). The similarity of these results to the results of the same

Table 3. Unadjusted mean outcome responses by experimental condition among participants who completed the trial.

	Text-only Mean (SD)	Graphic Images Mean (SD)	Graphic Images and Elaborated Text Mean (SD)	Omnibus Effect Size η_p^2
Negative Affect	4.52[A,B] (.87)	5.30[A] (1.14)	5.09[B] (1.27)	.08
[CI 95]	[4.27, 4.72]	[5.05, 5.54]	[4.84, 5.32]	
Risk Scrutiny	3.32[A,B] (1.30)	3.70[A] (1.19)	3.84[B] (1.07)	.03
[CI 95]	[3.03, 3.62]	[3.44, 3.96]	[3.60, 4.08]	
Perceived Credibility	6.16[A] (1.14)	6.51[A,B] (.70)	5.99[B] (1.17)	.04
[CI 95]	[5.90, 6.42]	[6.36, 6.66]	[5.73, 6.25]	
Quit Intentions (Standardized)	0.11 (.92)	-0.01 (.88)	-0.09 (.89)	.01
[CI 95]	[-.10, .32]	[-.20, .18]	[-.28, .11]	
Risk Perceptions (Average)	5.20 (1.29)	5.41 (1.27)	5.19 (1.38)	.01
[CI 95]	[4.90, 5.50]	[5.13, 5.69]	[4.89, 5.50]	
Label Memory at Week 6	3.92[A,B] (1.36)	4.98[A] (1.79)	5.13[B] (2.31)	.08
[CI 95]	[3.61, 4.23]	[4.59, 5.36]	[4.61, 5.64]	
Risk Knowledge at Week 6	3.61 (1.53)	4.09 (1.96)	3.88 (1.72)	.01
[CI 95]	[3.26, 3.96]	[3.66, 4.52]	[3.50, 4.27]	
Risk Knowledge at Follow-up	3.55 (1.32)	3.50 (1.54)	3.67 (1.64)	.00
[CI 95]	[3.18, 3.92]	[3.10, 3.90]	[3.26, 4.08]	

Shared superscripts indicate that values are significantly different, $p < .05$. Direct effects of condition on Risk Perceptions and Quit Intentions are based on average responses to relevant measures. An index of Quit Intentions reported in this table was created by averaging standardized responses to each of the three quit intention measures ($\alpha = .88$). An index of Risk Perceptions were created by averaging across the three risk perception measures ($\alpha = .70$).

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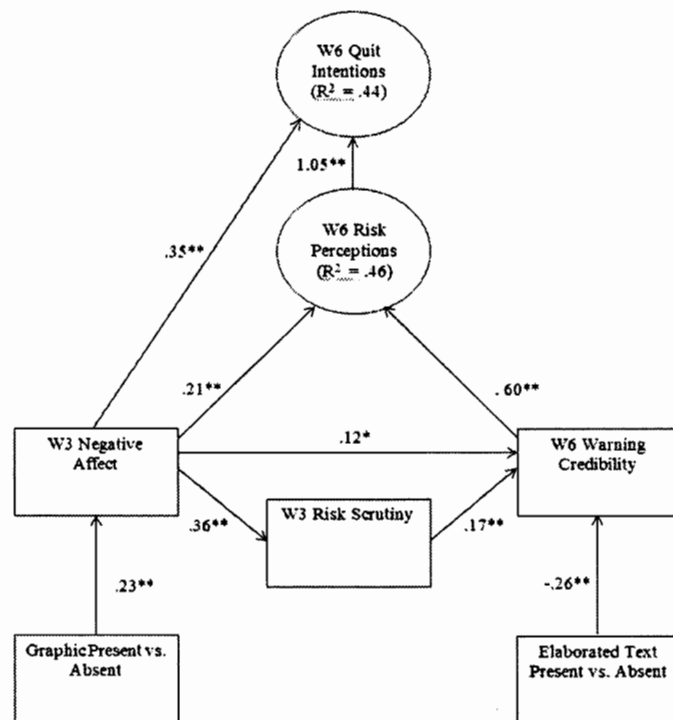
Fig 3. Model Testing the Predictions of Hypotheses 1 and 2. W3 = Week 3; W6 = Week 6. Path coefficients for the measurement models for Risk Perceptions (Risk 1 = 1.00, Risk 2 = .88**, Risk 3 = 1.19**) and Quit Intentions (Contemplation Ladder = 1.00, 30-Day Quit Intentions = .45**, Quit Desire = .42**)

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model estimated with MLR suggests that non-normal variable distributions did not significantly bias the trial's results. The AIC for this model was 8215.82 and the BIC was 8397.46. As predicted by H1a, warning labels with graphic images elicited more negative affect toward smoking than text-only warning labels at week 3 ($b = .23, p < .001$). Consistent with the affect heuristic, this led to heightened risk perceptions ($b = .21, p < .001$); negative affect also led to increased quit intentions independent of risk perceptions at week 6 ($b = .35, p = .004$). As predicted by H1b, negative affect also led to increased risk scrutiny at week 3 ($b = .36, p < .001$), which then led to heightened perceptions of warning credibility at week 6 ($b = .17, p = .009$). There was also a direct link between negative affect and heightened perceptions of warning credibility at week 6 ($b = .12, p = .033$). As predicted by H1b, warning credibility was a significant predictor of risk perceptions at week 6 ($b = .60, p < .001$). Finally, heightened risk perceptions predicted increased week 6 quit intentions ($b = 1.05, p < .001$). Contrary to H2, graphic warning labels with elaborated text were perceived as less credible at week 6 than graphic warnings with basic text only ($b = -.26, p = .001$).

All indirect paths in the final model were statistically significant, Table 4. The positive indirect effect of graphic presence -> negative affect ->risk perceptions ->quit intentions is consistent with the negative affect aroused by the presence of graphic images acting as a cue from which people infer risk (i.e., the Affect Heuristic [8]), which in turn leads to quit intentions. The positive indirect effect of graphic presence -> negative affect -> quit intentions indicates that affect influenced quit intentions apart from risk perception. The positive indirect effects of graphic presence -> negative affect -> risk scrutiny -> warning credibility -> risk perceptions -> quit intentions and graphic presence ->negative affect -> warning credibility -> risk

Table 4. Indirect effects of condition on risk perceptions and quit intentions.

Mediation Path	Indirect Effect (SE)
Affect Heuristic path (H1a): Graphic Present vs. Absent -> Negative Affect -> Risk Perceptions -> Quit Intentions	.050 (.019)
[CI 95]	[.019, .094]
Affect Motivates Quit Intentions: Graphic Present vs. Absent -> Negative Affect -> Quit Intentions	.079 (.030)
[CI 95]	[.021, .140]
Affect as Spotlight Motivates Greater Scrutiny of Message (H1b): Graphic Present vs. Absent -> Negative Affect -> Risk Scrutiny -> Warning Credibility -> Risk Perceptions -> Quit Intentions	.009 (.005)
[CI 95]	[.002, .020]
Affect Enhances Warning Credibility: Graphic Present vs. Absent -> Negative Affect -> Warning Credibility -> Risk Perceptions -> Quit Intentions	.018 (.010)
[CI 95]	[.021, .140]
Elaborated text and Warning Credibility (H2): Elaborated Text Present vs. Absent -> Warning Credibility -> Risk Perceptions -> Quit Intentions	-.165 (.056)
[CI 95]	[-.289, -.082]
Total indirect effect of Graphic Present vs. Absent on Quit Intentions	.155 (.038)
[CI 95]	[.085, .234]
Total indirect effect of Elaborated Text Present vs. Absent on Quit Intentions	-.165 (.056)
[CI 95]	[-.289, -.082]

Bold indicates a reliable indirect effect, where $p < .05$.

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perceptions -> quit intentions are consistent with images which arouse negative affect motivating more careful consideration of warning information (i.e., affect as a spotlight [11,12]). Finally, the negative indirect effect of elaborated text presence -> perceived credibility -> risk perceptions -> quit intentions suggests that the impact of affect on risk perceptions and quit intentions only occurs when people find the warnings credible, which was not the case with the warnings that included elaborated text.

Investigating the influence of attrition

Participants who completed the trial were older ($b = 2.21, p = .028$) and lighter smokers ($b = 3.27, p = .001$) than participants who did not complete the trial. Race, ethnicity, education, and other smoking characteristics were not significant predictors of attrition (for details of these analyses, see S2 Table). Participant age, self-reported number of cigarettes smoked daily, and all variables shown in Fig 3 were used to impute data for participants who were randomized to experimental conditions but did not complete the study and for items participants who completed the study declined to answer. Covariates were not included in the imputation model because the "smoking heaviness" covariate was derived from self-reported number of cigarettes smoked daily at baseline. These full data sets (n = 289) were then used to test the model presented in Fig 3. Control variables were included when imputed data were fit to the hypothesized model. The model fit the imputed data well, as evidenced by a non-significant χ^2 ($\chi^2[58]$ = 61.93, $p = .338$), a relative χ^2 of less than 2 (1.07), a low RMSEA (.02, CI 90: .00, .04), and high CFI and TLI values (1.00 and .99). All model paths remained significant, S4 Fig.

Testing alternative models

Although our hypothesized model fit the data well, we also tested two additional models derived from the predictions of alternative theoretical frameworks. Some researchers have suggested that graphic warning labels are effective primarily because they are more salient than text-only warnings [43]. In this account, image salience causes smokers to scrutinize risk information, and risk scrutiny increases negative affect, risk perceptions, and quit intentions [48]. We tested an alternative model consistent with this account, which reversed the order of risk scrutiny and negative affect. The data did not fit this model as well as our final model, $\chi^2(58) =$ 98.84, $p < .001$, relative $\chi^2 = 1.70$, RMSEA = .05 (CI 90: .04 to .07), CFI = .95, TLI = .93. The AIC (8251.73) and BIC (8433.37) were larger for this model than our hypothesized model ($AIC_{Difference} = 35.91$; $BIC_{Difference} = 35.91$), which further suggests that the data did not fit this model as well as it fit our hypothesized model. Path coefficients for this model are available to interested readers in S5 Fig.

Self-perception theory, derived from the psychological literature on attitude change, suggests that people often infer their beliefs from their decisions [49]. Within the context of graphic warnings labels, this perspective would suggest that smokers may infer their risk perceptions from observing their stated quit intentions. We tested an alternative model in which risk perceptions were predicted by quit intentions rather than the reverse. All paths in this alternative model were identical, except the location of the two latent constructs was reversed, such that quit intentions were predicted by negative affect and warning credibility and risk perceptions were predicted by negative affect and quit intentions. The data did not fit this model as well as our final model, $\chi^2(58) = 104.49$, $p < .001$, relative $\chi^2 = 1.80$, RMSEA = .06 (CI 90: .04 to .08), CFI = .94, TLI = .92. The AIC (8257.38) and BIC (8439.02) were larger for this model than our hypothesized model ($AIC_{Difference} = 41.56$; $BIC_{Difference} = 41.56$), which further suggests that the data did not fit this model as well as it fit our hypothesized model. Path coefficients for this model are available to interested readers in S6 Fig.

After examining two plausible alternative models derived from past research, we concluded that the model which tested Hypotheses 1 and 2 fit the data comparatively better. This suggest that the present paper's theoretical conception of how graphic warning labels influence smokers' risk perceptions and quit intentions provides a better account of the data in this randomized clinical trial than the alternative theories. Further, these analyses suggest that the temporal relationships we hypothesized provide a better explanation for the data than alternative relationships.

Hypothesis 3

We proposed that graphic warning labels would be more memorable than text-only warnings (due to the increased negative affect towards smoking or to the presence of more detailed risk information), and that this increased memory for warning information would lead to greater smoking risk knowledge. Existing literature suggests that increased memory for warning information could be driven by the negative affect aroused by images. However, in the current research, negative affect was not correlated with label memory or risk knowledge, Table 5, precluding the possibility that negative affect mediates the impact of graphic images on memory. The second contrast comparing the presence of elaborated text (1) to the other two warning conditions (-1) was also uncorrelated with memory for warning information (see Table 5). Thus, we used the contrast of the two graphic conditions (coded as 1) with the text-only warnings (coded as -2) to investigate the impact of images on label memory on risk knowledge immediately after completing the trial and at follow-up.

When estimated using maximum likelihood with robust standard errors, the model which examined graphic image presence -> label memory at week 6 -> risk knowledge at week 6

Table 5. Correlations among key measures.

	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
1. Graphic Present vs. Absent	-									
2. Elaborated Text Present vs. Absent	-.01	-								
3. Negative Affect	.27**	-.08	-							
4. Risk Scrutiny	.17**	.05	.34**	-						
5. Perceived Credibility	.04	-.21**	.22**	.24**	-					
6. Mean Risk Perceptions	.04	-.07	.32**	.23**	.55**	-				
7. Mean Quit Intentions	-.08	-.04	.36**	.16*	.37**	.48**	-			
8. Label Memory at Week 6	.27**	.03	.09	.10	.08	.10	.04	-		
9. Risk Knowledge at Week 6	.10	-.05	.02	.04	.07	.04	.10	.16*	-	
10. Risk Knowledge at Follow-up	.01	.05	.02	.02	-.07	-.01	-.01	.17*	.43**	-

*$p < .05$.

**$p < .01$.

Mean Quit Intentions include scores with week 5 values carried forward for the 22 data points where week 6 quit intentions were not recorded due to computer error.

provided an adequate fit to the data as evidenced by a non-significant χ^2 (1) = 1.525, p = .217, a relative $\chi^2 < 2$ (1.525), a low RMSEA (.047, CI 90: .000, .185), and high a CFI (.98). Unexpectedly, the TLI value was below the threshold for good model fit (TLI = .85). Fit statistics were similar when this model was rerun using bootstrapping (χ^2[1] = 1.389, p = .239, relative χ^2 = 1.389, RMSEA = .04 [CI 90: .00 to .18], CFI = .99, TLI = .88), suggesting that non-normal variable distributions did not significantly bias results. Image presence led to increased label memory at week 6 (b = .37, $p < .001$), and label memory led to increased smoking risk knowledge immediately after participants had completed the trial (b = .14, p = .010). Bootstrapping analysis revealed that this indirect effect was significant (Estimated Indirect Effect = .05 [SE = .02], CI 95: .010, .097). The model explained 7.1% of differences in risk knowledge at week 6 (R^2 = .071)

The model which examined graphic image presence ->label memory -> smoking risk knowledge at follow up (for the 169 participants who completed the follow-up) also fit the data acceptably when estimated using maximum likelihood with robust standard errors, χ^2(1) = .07, p = .787, $\chi^2_{relative}$ = .07, RMSEA = .00 (CI 90 .00 to .11), CFI = 1.00, TLI = 1.38). Model fit was similar when this model was rerun using bootstrapping, χ^2(1) = .06, p = .805, relative χ^2 = .06, RMSEA = .00 (CI 90: .00 to .11), CFI = 1.00, TLI = 1.41, suggesting that non-normal variable distributions did not significantly bias results. For this subgroup, image presence predicted label memory at week 6 (b = .37, $p < .001$), and label memory predicted smoking risk knowledge at follow up (b = .14, p = .025). This indirect effect was significant (Estimated Indirect Effect = .05 [SE = .02], CI 95: .008, .103). The model explained 6.6% of differences in risk knowledge at follow-up (R^2 = .066).

Investigating the influence of attrition. To investigate the possibility that differences in attrition might account for the effects of label memory on smoking risk knowledge, we imputed memory data for participants who did not complete the trial or declined to respond to these items. Participant age and self-reported number of cigarettes smoked daily (both significantly associated with attrition), experimental condition, and available label memory and risk knowledge data were used to create 10 complete data sets. These full data sets (n = 289) were then used to retest the models for hypothesis 3. The χ^2, relative χ^2, and RMSEA suggest that the imputed data sets also provided a good fit to our model predicting smoking risk knowledge at

week 6 ($\chi^2[7]$ = 12.04, p = .099, relative χ^2 = 1.72, RMSEA = .05 [CI 90: .00 to .10]). Unexpectedly, the CFI and TLI did not, CFI = .80, TLI = .75). All fit statistics suggest that the full data sets provided a good fit to our model predicting smoking risk knowledge at follow-up ($\chi^2[7]$ = 6.53, p = .479, RMSEA = .00 [CI 90: .00 to .07], CFI = 1.00, TLI = 1.04). Path coefficients for these imputed models were similar in magnitude to the values in models that only included participants who completed the assessments, S7 Fig. Thus, these tests suggest that attrition does not account for the impact of graphic warnings on smoking risk knowledge.

Discussion

The current research represents the first experimental investigation in a naturalistic setting of the psychological processes by which graphic warning labels influence smokers' affect and cognitions regarding their habit. As such, it represents the best to-date approximation of real world impact of graphic warning labels. In the study, graphic warning labels (compared to text-only) increased negative affect toward smoking, elicited greater scrutiny of the warning message, and enhanced label memory. The graphic-only condition also increased the credibility of the warning message. In analyses of mediated effects on perceived risks of smoking and intentions to quit, we found support for H1a and H1b that multiple functions of affect influenced these outcomes [11, 12]. Warnings with graphics did, in fact, elicit more negative affect than text-only warnings, and, consistent with past research on the affect heuristic [8], more negative affect increased risk perceptions (and quit intentions in turn). Increased negative affect also motivated greater quit intentions directly. Third, it also elicited greater scrutiny of the messages and increased perceptions of warning credibility. This result is consistent with affect acting as a spotlight and motivating greater processing of the risk information consistent with that negative affect. In addition, increased credibility perceptions led to heightened risk perceptions and quit intentions. The elaborated text condition, however, did not support H2 and, instead, reduced credibility perceptions and counteracted the images' effect on heightened risk perceptions.

Consistent with H3, the presence of graphic images also increased memory for label content, which led to greater smoking risk knowledge immediately after participants completed the trial and approximately one month later. Thus, warnings containing images also enhanced memory for label content, which helped to educate smokers about the harms of smoking. Although we predicted that negative affect from week 3 would drive increased memory for warning information at week 6 [18, 19], the data were inconsistent with this prediction. Several possible reasons exist for this lack of effect: (1) negative affect may have already started to fade after a week of exposure [24, 25], (2) the negative affect measure focused on feelings about smoking rather than feelings about the warnings themselves, and (3) the measure focused on valence rather than on the arousal linked with memory in past studies [18, 19]. The first possibility seems unlikely given that negative affect remained strong enough to have significant associations with several other key variables. Alternatively, it may be the case that negative affect is unrelated to memory for warning information. Instead, it may be that simply having illustrations of textual material provided more detailed content that enhanced memory [50]. Given that the images used in cigarette warnings were designed to illustrate the health risks, they likely provide memory cues for the warning information. Additional research is needed to determine how to maximize the memorability of health risk information on warnings.

Results of the current research replicate past laboratory findings which have found that the negative affect elicited by graphic warning labels mediates their effect on quit intentions [6, 13, 27]. The current research extends these past investigations by demonstrating that negative affect has significant influences outside the laboratory setting and after many exposures to the

warnings. Importantly, results of the current research also provide evidence that images which arouse negative affect may be necessary components of impactful cigarette warning labels where impact is defined as increased risk knowledge, risk perceptions, and quit intentions (see also Wang et al. [51]). In this study, negative affect influenced risk perceptions directly, serving as a simple cue or heuristic. However, negative affect also caused people to more carefully scrutinize smoking-risk information and led to greater perceived label credibility, risk perceptions, and quit intentions. This careful assessment of available information is inconsistent with the labels merely ". . .browbeat[ing] consumers into quitting" [3]. The impact of negative affect suggests that merely making text-only warnings more salient or including images which do not evoke negative affect may be insufficient to increase smokers' risk perceptions and quit intentions.

Although the tobacco companies assert that "Americans. . .are well aware of the health risks of smoking" [3], providing risk information in plain text is less effective than text plus images. Even after exposure to the newly mandated text warnings, participants in this study were able to identify only 3–4 smoking-related risks on average (Table 3). The 2014 Surgeon General's Report states that smoking harms nearly every organ in the body and identifies at least 35 discrete negative health outcomes caused by smoking [52]. Exposure to warning labels which included graphic images, however, led to greater label memory which was associated, in turn, with increased knowledge of smoking-related risks both at the study's end and one month later. These findings demonstrate that graphic warning labels can be effective in increasing knowledge about smoking's dangers, perhaps consistent with research showing the superiority of information accompanied by illustration for enhancing recall of that information [50].

The effects of our warning-label manipulations on smoking risk knowledge, risk perceptions, and quit intentions were indirect and without a significant unmediated effect. Our trial was powered on the expectation of a larger warning label effects on quit intentions than we observed. Additionally, our final sample of 244 analyzed participants falls slightly below our recruitment goal. Nevertheless, the mediated analyses suggest that with a larger sample, experimental effects on quit intentions may have emerged alongside the observed direct effects on affect, label scrutiny, and label credibility. In addition, our finding of a direct effect on label memory suggests that risk knowledge may also be enhanced. It remains for future research with larger samples to demonstrate this conclusively.

Indirect-only effects like those observed in this trial are also important because they suggest the possibility of missing moderators [53]. For example, in the current research, reactance to label content is one possible missing moderator [54]. Such reactance could be the cause of the reduced credibility elicited by the elaborated text condition. Although earlier research has shown that elaborated text such as that used in Canada can enhance warning effects [13], this study's exclusive focus (in the elaborated text condition) on the very next cigarette entailing risk may have been met with disbelief among life-long smokers who began the study with no intentions to quit. The current research suggests that either additional research is needed to identify the best content for the elaborated text, or that the positive effects of such text are limited to studies with a single exposure to any one warning [13, 35]. Alternatively, the smaller text size in the elaborated-text condition may have been problematic as observational research has demonstrated that warning labels with large, salient text are more impactful than those with smaller and less salient text [55].

Some of our design choices also may have reduced our effect sizes. First, the relatively brief study duration (four weeks) may be inadequate to compete with the power of addiction. Longer trials are expensive, but may be necessary. Second, we chose to use the nine images selected by the FDA for placement on US cigarette packages in their 2011 Final Rule [26]. The images in these warnings are less arousing than those featured on cigarette packages in other countries

[56]. Single exposure studies and population level research suggest that placing more disturbing images on graphic warning labels would increase their impact on intentions to change behaviors [51, 56]. Thus, the use of more graphic warnings than those used in the present trial may reveal larger effects. Third, we did not have a true control condition. Participants in the text-only condition received novel warnings that were stronger than those currently featured on US cigarette packaging. In particular, text-only participants received the nine, currently unfamiliar, risk statements mandated by the Family Smoking Prevention and Tobacco Control Act, printed in black text on a white background. Current US warnings are smaller and in colors consistent with the rest of the package. Although we believe that the inclusion of a strong comparison condition is a merit of the current research, our results might have appeared stronger if we had instead compared image conditions to a "current warnings" control group.

The current research was designed to investigate how graphic warning labels might influence smokers at the population level. As such, this trial lacked sufficient statistical power to effectively identify the impact of potential moderating variables. Although past experimental research suggests that the effects of graphic warnings do not vary as a function of demographic characteristics such as race/ethnicity, education, and income [47], this result may prove to be different with a period of prolonged exposure. This possibility should be explored in future research. Some additional variables which future research should consider as potential moderators of the effects observed here include the number of cigarettes participants' smoke daily, nicotine dependence, duration of smoking, living with a smoker, and personal experience with smoking-related illness. Another plausible moderator is baseline quit intentions. For this study, we only recruited participants who indicated that they were either "somewhat unlikely" or "very unlikely" to quit smoking in the next 30 days during the prescreening phone call. It is possible that graphic warnings might be more impactful for smokers planning to quit in the near future.

This study is the first experiment of which we are aware to investigate the processes by which graphic warning labels influence smokers in a naturalistic setting over an extended period of time. Our method of providing relabeled cigarettes ensured that all participants were exposed to experimental warning labels every time they smoked one of their own cigarettes. However, it is possible that providing participants with cigarettes at no cost may have undermined interest in quitting and worked against our hypotheses (see Table 2). Recent investigations suggest that this can be avoided by requiring participants to provide cigarettes for relabeling [57] or asking participants to apply experimental labels to their own cigarettes [58]. These techniques may reduce one source of error variance, however, while increasing others (e.g., participant lack of funds or compliance). In addition, if free cigarettes provided disincentive to quit, quit intentions at least should have been influenced equally across all conditions. Overall, the presence of the effects we found speaks to the efficacy of graphic warning labels. Additional investigations are needed to determine the tradeoffs of different methods by which to examine the impact of graphic warning labels in naturalistic contexts.

In particular, the current research provides evidence that negative affect is a crucial ingredient in successful graphic warning labels. It is also the first study to demonstrate that graphic warning labels can elicit greater processing of provided smoking risk information rather than influencing smokers exclusively by "browbeating" them into quitting. Policies requiring such labels have the potential to reduce the number of Americans who smoke. The affect induced by graphic warning labels appears to have utility in communicating more and more credible information, useful to promoting risk perceptions and quit intentions among smokers in the US and around the world.

Supporting Information

S1 Checklist. CONSORT Checklist.
(DOC)

S1 Fig. Basic Text Warnings. Basic text warnings which were affixed to the side of all cigarette packages distributed in the study. These were the only warning labels affixed to the packages of participants in the text-only condition.
(PDF)

S2 Fig. Graphic Warning Labels. Graphic warnings labels were taken from the 2011 FDA final rule. Participants in the graphic images plus basic text condition received these image-text pairings.
(PDF)

S3 Fig. Elaborated Text Warning Labels. Graphic warning label images taken from the 2011 FDA final rule modified to include elaborated text. Participants in the graphic image plus elaborated text condition received these warning labels.
(PDF)

S4 Fig. Model Testing the Predictions of Hypotheses 1 and 2 with Imputed Data. W3 = Week 3; W6 = Week 6. Model fit statistics: $\chi^2(58) = 61.93$, p = .338, relative $\chi^2 = 1.09$, RMSEA = .02 [CI90: .00, .04]; CFI = 1.00; TLI = .99). Path coefficients for the measurement models for Risk Perceptions (Risk 1 = 1.00, Risk 2 = .92**, Risk 3 = 1.21**) and Quit Intentions (Contemplation Ladder = 1.00, 30-Day Quit Intentions = .45**, Quit Desire = .42**).
(PDF)

S5 Fig. Model Testing the Predictions of Alternative Model 1. W3 = Week 3; W6 = Week 6. Model fit statistics: $\chi^2(58) = 98.84$, p = .001, relative $\chi^2 = 1.70$, RMSEA = .05 [CI90: .04, .07]; CFI = .95; TLI = .93, AIC = 8251.73, BIC = 8433.37. Path coefficients for the measurement models for Risk Perceptions (Risk 1 = 1.00, Risk 2 = .87**, Risk 3 = 1.15**) and Quit Intentions (Contemplation Ladder = 1.00, 30-Day Quit Intentions = .45**, Quit Desire = .41**).
(PDF)

S6 Fig. Model Testing the Predictions of Alternative Model 2. W3 = Week 3; W6 = Week 6. Model fit statistics: $\chi^2(58) = 104.49$, p < .001, relative $\chi^2 = 1.80$, RMSEA = .06 [CI90: .04, .08]; CFI = .94; TLI = .92, AIC = 8251.73, BIC = 8433.37. Path coefficients for the measurement models for Quit Intentions (Contemplation Ladder = 1.00, 30-Day Quit Intentions = .45**, Quit Desire = .42**) and Risk Perceptions (Risk 1 = 1.00, Risk 2 = .86**, Risk 3 = 1.16**).
(PDF)

S7 Fig. Models Testing Hypothesis 3 with Imputed Data. Top: Image presence vs. absence on risk knowledge at week 6 with imputed data, $\chi^2(7) = 12.04$, p = .099, RMSEA = .05 (CI 90: .00 to .10), CFI = .80, TLI = .75. Bottom: Image presence vs. absence on risk knowledge at 1 month with imputed data, $\chi^2(7) = 6.53$, p = .479, RMSEA = .00 (CI 90: .00 to .07), CFI = 1.00, TLI = 1.04.
(PDF)

S1 File. Analyzed Data File.
(XLS)

S1 Protocol. Complete Trial Protocol.
(DOCX)

S1 Table. Demographics of Included Participants by Experimental Condition at Randomization.
(PDF)

S2 Table. Demographic Differences Between Participants Randomized to Conditions Who Did vs. Did Not Complete the Trial.
(PDF)

Author Contributions

Conceived and designed the experiments: DR EP AS. Performed the experiments: LE KS. Analyzed the data: AE. Wrote the paper: AE EP. Reviewed and commented on the scientific content of the paper: AE EP AS LE KS DR.

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Article

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Warning labels formulated as questions positively influence smoking-related risk perception

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Abstract
Research on warning labels printed on cigarette packages has shown that fear inducing health warnings might provoke defensive responses. This study investigated whether reformulating statements into questions could avoid defensive reactions. Smokers were presented with either warning labels formulated as questions, textual warning labels, graphic warning labels, or no warning labels. Participants' smoking-related risk perception was higher after exposure to warning labels formulated as questions or no warning labels than after exposure to textual or graphic warning labels. These results indicate that reformulating statements into questions can avoid defensive responses elicited by textual- and graphic warning labels.

Keywords
risk perception, self-persuasion, smoking, warning labels

Introduction

Although smoking has tremendous health consequences (e.g. Doll et al., 2004), and is one of the leading causes of preventable death (World Health Organization, 2003), people continue to smoke. Therefore, governments attempt to discourage smoking by different means. Warning labels printed on cigarette packages is a popular mean that has been introduced worldwide. Warning labels provide information about the health-damaging consequences through textual statements, and in some countries, the textual information is presented together with deterrent pictures that illustrate the smoking-related diseases graphically. These warning labels are designed to inform people about the negative consequences of smoking (Strahan et al., 2002), and should thereby increase the smoking-related risk perception. Research has shown that current warning labels induce threat, and are perceived as scary even when the arguments are not directly related to death (Hansen et al., 2010). In this way, they operate as fear appeals,

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which are defined as persuasive communication that should – via the induced fear – lead to self-protective actions (e.g. Rogers, 1983). Thus, the increased smoking-related risk perception is assumed to elicit self-protective actions, which could involve changing attitudes and the corresponding behavior. Attitudes and the corresponding behavior are suggested to change when people perceive a threat, and simultaneously perceive that they are highly efficient in changing their behavior (e.g. Ajzen, 1985; Marks, 1998; Schwarzer, 1992; Schwarzer and Fuchs, 1996; Strahan et al., 2002; Witte, 1992). Thus, warning labels do not only contain negative, fear inducing information concerning the health consequences of smoking, but also information about facilities that can be contacted to get help when trying to quit smoking. In this process of changing attitudes and behavior, outcome expectancies are crucial (Marks, 1998; Schwarzer, 1992; Schwarzer and Fuchs, 1996; Strahan et al., 2002). Therefore, warning labels provide additional information about the positive outcomes of quitting smoking.

The points for current health campaigns mentioned above are combined in present warning labels. However, empirical research has provided inconsistent results about their effectiveness. On the one side, studies suggest that warning labels on cigarette packages are effective (e.g. Borland et al., 2009; Hammond et al., 2003, 2004, 2006; Kees et al., 2010; O'Hegarty et al., 2006). For example, Hammond and colleagues (2004) conducted a telephone survey after the introduction of combined warning labels and found that 20% of the participating smokers reported that they smoked less because of the new warning labels. In another survey study (Hammond et al., 2003), smokers were asked how often they thought about the warning labels, and whether they discussed them with other people. The authors found that smokers who engaged in thinking about the warning labels reported that they were more willing to quit smoking, tried more often to quit smoking or smoked less. However, results of these surveys rely on self-reports and may thus be

unreliable, as 'saying is not (always) doing' (Ruiter and Kok, 2005). As smoking is forbidden in many public places and a stigmatized behavior (Swanson et al., 2001), it seems plausible that smokers would report to smoke less than they actually do to leave a better impression. Furthermore, the studies outlined above did not use experimental designs; a fact that should be considered before starting health campaigns (Whittingham et al., 2008).

On the other side, experimental studies find evidence for possible negative outcomes like defensive responses (e.g. Glock and Kneer, 2009; Harris et al., 2007; Wedburg, 2006), psychological reactance (e.g. Erceg-Hum and Steed, 2011; Wiuns et al., 2009), or no effectiveness at all (Petersen and Linder, 2006). There is even some research arguing against fear appeals in warning labels, as they may result in defiance, and decreased probability of changing attitudes and behavior (Hastings and MacFadyen, 2002; Ruiter and Kok, 2005). Thus, it seems that threatening anti-smoking warning labels might have unintended consequences, namely a decreased smoking-related risk perception among smokers. Thereby, it may become less likely that smokers accept anti-smoking messages in warning labels. The present research investigates how these unintended consequences can be avoided.

Defensive responses are well documented in fear appeal research. Research suggests that the combination of fear arousal with high personal relevance is an important determinant of defensive responses (e.g. Jepson and Chaiken, 1990; Liberman and Chaiken, 1992). People who feel fear and perceive high personal relevance might have the motivation to defend themselves against the threat, which is assumed to stem from the need to protect the self-image (Sherman et al., 2000). This may be especially true for smokers, as smoking and the corresponding health consequences are highly important for them, and the negative health consequences and a high risk perception are the number one reasons for quitting smoking (Gibbons et al., 1991; Klesges et al., 1988).

Furthermore, risk perception could also be an indicator for defensive responses, as risk perception changes as a function of the need to protect self-image and self-esteem. For instance, risk perception decreases after relapse (Gibbons et al., 1997). Abolishing warning labels might reduce defensive responses because there is no information smokers would have to defend against. Additionally, smoking-related risk perception is already high among smokers (Glock and Kneer, 2009; Hahn and Renner, 1998). Smokers are aware of the fact that smoking increases the risk of cancer (Hermand et al., 1997), and of other negative health consequences (Louka et al., 2006). Forbearing from confronting smokers with fear arousing warning labels makes defensive responses unnecessary. However, abolishing warning labels seems not to be appropriate because this would lead to less informed smokers.

Another and possibly more effective way of reducing threat and fear in warning labels may be to redesign the warning labels that are currently used. Research on persuasion has shown that arguments individuals generate themselves are more convincing than arguments provided by external sources (i.e. information provided from other people), as people tend to trust themselves more than external sources, whose information they are more likely to adjust according to personal views (Mussweiler and Neumann, 2000). Self-generated arguments are often perceived as more accurate (Hoch and Deighton, 1989; Levin et al., 1988) than information that is provided from somebody else. Furthermore, confronting people with external behavior instructions (i.e. another person tells people what they have to do) threatens their freedom to choose, which may result in defiance (Brehm and Sensenig, 1966; Grandpre et al., 2003). Additionally, research on persuasion has provided evidence for different influences on the persuasiveness of an argument depending on whether the argument leads to explicit or implicit conclusions (Kardes et al., 1994). Explicitly stated arguments are not susceptible to interpretations and the perceiver may feel that an external source tells him what to believe. This might lead to resentment, which in turn leads to counter-argumentation (Clee and Wicklund, 1980; O'Keefe, 1997). In contrast, arguments that imply a particular conclusion but give the perceiver the possibility to draw the conclusion himself may reduce feelings of resentment (Kardes et al., 1994). In this sense, arguments provided on current warning labels can be considered as explicit conclusions; an external source tells smokers what they have to believe and to do which leads to counter-argumentations. Contrarily, anti-smoking arguments which lead to implicit conclusions might be more effective, particularly when the knowledge about the health consequences is high (Kardes et al., 1994). Therefore, when developing new warning labels one should pay attention to three important aspects: (1) warning labels should not expose smokers to fear inducing anti-smoking arguments; (2) behavior instructions provided by an external source should be avoided (except if they increase self-efficacy; see Witte, 1992); and (3) warning labels should stimulate smokers to generate anti-smoking arguments themselves. Additionally, we know from self-perception theory that people often observe their behaviors to infer their attitudes, especially in situations in which they are not exactly sure what to believe about a particular topic (e.g. Bem, 1967). Just like an outside observer, people draw conclusions about their attitudes from what they are doing. For example, smokers may evaluate smoking as more negative when they observe themselves finding arguments against smoking.

One way to elicit that smokers generate arguments against smoking could be the use of questions in warning labels. Müller and colleagues (2009), as well as Ritter and colleagues (2012) investigated the role of questions in anti-smoking campaigns and found them to be more effective in influencing short-term smoking behavior than anti-smoking arguments provided from an external source. The present study extends this line of research by investigating smoking-related risk perception after being presented with warning labels formulated as

Table 1. Mean scores and standard errors in parentheses on personal characteristics. All $F_{(1, 56)} < 1$, NS

Experimental group	Years smoked	Number of cigarettes smoked per day
Question (N = 15)	4.90 (1.15)	8.73 (1.43)
Text (N = 15)	6.33 (1.15)	11.33 (1.43)
Picture (N = 15)	7.17 (1.15)	11.47 (1.43)
Control (N = 15)	5.97 (1.15)	11.20 (1.43)

questions compared to warning labels formulated as statements or graphic warning labels.

Based on the previously mentioned theories and empirical findings, we expected that the textual and graphic warning labels, which are designed to induce fear, would lead to defensive responses. In contrast, no warning labels and warning labels formulated as questions should not induce fear and, thereby, should make defensive responses unnecessary. We hypothesized that smoking-related risk perception will be higher among smokers who were not confronted with warning labels, or were confronted with warning labels formulated as questions compared to smokers who were presented with the current textual and graphic warning labels.

Methods

Participants and design

A single factor design (warning label: textual as questions vs control vs graphic vs textual as statements) was used, with warning labels serving as between-subjects factor. Sixty students (14 male, 46 female) from the Saarland University/Germany, participated in this study; their age range was 18–46 ($M = 23.03$, SD = 4.46). All participants were daily smokers: 23.3% smoked 1–5 cigarettes/day, 36.7% smoked 6–10 cigarettes/day, 38.3% smoked 11–20 cigarettes/day, and 1.7% smoked more than 20 cigarettes/day. They received credit points or financial compensation for participation, and were randomly assigned to one of the four experimental conditions. Furthermore, it was checked whether the four groups differed

in personal characteristics (years smoked, mean number of cigarettes smoked per day), no significant differences were found (Table 1).

Procedure and materials

Upon arrival, participants were asked to fill in a questionnaire assessing their age, the number of cigarettes they smoked daily, and the number of years since they started smoking. Subsequently, seated in front of a computer screen, participants were presented with the warning labels (see Fig. 1): 15 participants received textual warning labels that were formulated as statements. In the textual warning labels condition, we used the 15 textual warning labels that are used on cigarette packages in Germany. Fifteen participants received graphic warning labels, which were preselected from a set of 32 graphic warning labels.[1] Graphic warning labels were presented without text information to avoid confounding of textual and graphical effects. Furthermore, another 15 participants received textual warning labels that were formulated as questions. To construct the question warning labels, we relied on the current textual warning labels and reformulated them as questions. For instance, 'Smoking causes fatal lung cancer' was changed into 'What are the consequences of smoking for your lung?'

Each warning label group was presented with 15 warning labels, each displayed for 3000 ms. A fourth group of 15 participants functioned as control group and received no warning labels. After this first phase, participants were asked to evaluate the likelihood of developing one of six smoking-related diseases during their lifespan, which indicated their smoking-related

Figure 1. Examples of the used warning labels

risk perception. All diseases presented had a clear relation to smoking.[2] In the current experiment, participants could indicate their risk on a scale from 0 (no risk at all) to 9 (highest risk). At the end, participants were thanked, paid, and debriefed.

Results

To assess smoking-related risk perception, a mean score of the answers on the six smoking-related diseases was calculated (α = .88). One participant was excluded from further analysis, as there was no variance in his responses, suggesting that he simply pressed a button without taking the question into consideration. To test our hypothesis that being confronted with questions or no warning labels would lead to a higher risk perception than when being confronted with statements or graphic warning labels, we computed one a priori contrast comparing the question and control conditions with the graphic and statement conditions, using the mean score as dependent variable.

The contrast revealed a significant effect on participants' perceived smoking-related risk perception, $F(1, 55)$ = 4.32, p = .04, ηp^2 = .07 (see Fig. 2). To test our assumption that neither

the control group differed from the question warning labels group, nor the graphic warning labels differed from the statement warning labels group in their smoking-related risk perception, we conducted two single effects tests. There was no difference between the question condition (M = 6.4, SD = 1.70) and the control condition (M = 6.05, SD = 1.44), $t(28)$ = 0.61, d = 0.22, p = .54, nor between the statement condition (M = 5.54, SD = 1.91) and the graphic condition (M = 5.01, SD = 1.95), $t(27)$ = 0.73, d = 0.27, p = .47 (Fig. 2).

Discussion

The warning labels formulated as questions resulted in higher smoking-related risk perception than the warning labels formulated as statements and the graphic warning labels. Thus, asking questions in warning labels seems to have some advantages. The literature shows that self-generated arguments are more convincing than arguments provided by an external source (Maurweiler and Neumann, 2000). Thus, arguments provided by current warning labels may work less effectively because they are provided by an external source. Questions however, result in arguments derived from the smokers
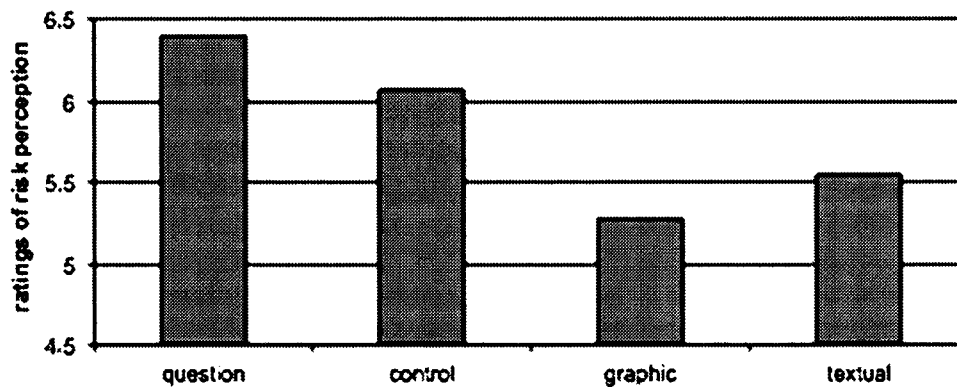
Figure 2. Mean score of smoking-related risk perception

themselves. Thereby, defensive responses can be avoided as the answer to the questions can be as fear inducing as the reader allows it to be. Hence, the answer to the question about the consequences of smoking for the lung does not necessarily need to be lung cancer, but could also be a slight cough, which is clearly less fear inducing. Although anti-smoking warning labels should induce fear and research has provided evidence for their threatening content (Hansen et al., 2010), we did not ask our participants whether they perceived the presented warning labels as fear inducing or not. It seems possible that warning labels induce worry, which is positively related to self-protective behaviors (Hay et al., 2006). Further research should introduce a measure of perceived fear and/or worry to answer this question. Nevertheless, given our results, warning labels formulated as questions might have induced worry, and thus reduced possible defensive responses. Furthermore, our results extend recent research showing that thinking about the consequences of smoking prolongs smokers' short-term abstinence (Müller et al., 2009; Ritter et al., 2012). Our findings could provide an explanation of why questions in warning labels reduce short-term smoking behavior. Warning labels formulated as questions increase smoking-related risk perception, which might in turn lead to short-term abstinence. Risk perception is an important step in building a motivation to quit; however it is of

course not sufficient for behavior change (Schwarzer, 1992; Schwarzer and Fuchs, 1996). Thus, we only assessed one factor that seems to contribute to quitting, and that might be an explanation for short-term abstinence as a function of questions. Future research should assess other variables like the intention to quit, or perceived self-efficacy to investigate which type of warning labels has an influence on these variables, and to get further insight into the processes behind risk perception or short-term abstinence.

In the present study, presenting no warning labels had the same effect as presenting questions. We assumed that in our control condition, no fear inducing information was presented and therefore, smokers had not to defend against the information. Thus, the control condition shows the smoking-related risk perception uninfluenced by any kind of information. The question may be asked why we then need questions in warning labels, when no warning labels have the same effect. Abolishing warning labels is not appropriate as this would lead to less informed smokers. Because questions seem to work better than textual and graphic warning labels, they may be seen as a promising alternative that could be added to existing warnings to keep the smoking-related risk perception high, and at the same time making smokers still aware of the negative consequences of their addiction. This combination could be valuable as the reception

of anti-smoking arguments provides smokers, and future generations of smokers with information about the negative consequences of smoking. However, anti-smoking messages are unpleasant for smokers and they might seek to avoid this information. Therefore, questions should be added, as being asked about the health risks might induce a deeper cognitive elaboration. Merely providing anti-smoking arguments might prevent people from thinking about the health consequences of their behavior.

Some limitations of the study have to be considered. First, our participants were all undergraduates. Although college smokers might be at risk to become regular and heavy smokers (Simmons and Brandon, 2007), in their college years they smoke at lower rates than older adults (Rigotti et al., 2000). Maybe, health consequences emphasized by current and graphic warning labels may not be relevant for these young smokers as they might know that these health consequences will not become important in the next few years, but just after many years of continued smoking. Thus, future research should focus on smokers who smoke for a longer period than undergraduates to investigate whether warning lables formulated as questions also increase their risk perception. A second point is related to our college smoker sample. As undergraduates, our smokers all had access to higher education. Hence, the question arises whether smokers with lower educational levels are as well informed about the smoking risks as smokers with higher educational levels. Smoking is more prevalent in individuals with low income (e.g. Lee et al., 2008). Although health risk perception seems to be independent of socioeconomic status and educational level (e.g. Lee et al., 2008; Weinstein, 1987), there might be differences among these individuals when it comes to the personal health risk (Ayanian and Cleary, 1999). A study conducted in Germany has shown that smokers with lower education perceive a lower personal smoking-related health risk than smokers with higher education (Pragst, 2011). Thus, smokers with low educational levels may not provide as many arguments against smoking as smokers with higher educational levels. Therefore, questions in warning labels should only be an addition to current warnings providing arguments about the health damaging consequences of smoking. Future research should focus on this issue and take smokers with different educational levels into account.

Second, the information provided on textual and graphic warning labels is well known by now. Hence, reading and looking at current warning labels does not inform smokers about something unknown (Hastings and MacFadyen, 2002). Getting asked questions while looking at and reading warning labels is a new procedure smokers are not familiar with. Thus, an alternative explanation of our findings might be that the novelty of the question warning labels drives the effect, that is, that the questions only work because they are new. However, in Germany, where the experiment took place, graphic warning labels are not yet introduced. This means that the smokers participating in the current study were neither familiar with the graphic warning labels, nor with the questions, which speaks against the novelty explanation. Nevertheless, future research should focus on the influence of the question warning labels in the long run. For example, it would be interesting to investigate possible habituation effects after repeated exposure, and the influence on long-term smoking behavior. Additionally, it would be advisable for a follow-up study to use a larger sample, which would make it possible to explore whether our effects differ between groups (e.g. light vs heavy smokers, people who have just started smoking vs people who have smoked for a couple of years).

Third, we used risk perception as an indicator for defensive responses (Gibbons et al., 1997), and indirectly as a measure of reactance. Thus, our study does not provide insight into the psychological processes during reception of warning labels and risk perception. Further research should use a direct measure of psychological reactance such as negative cognitions, threat to

perceived freedom to choice, or anger (Dillard and Shen, 2005; Quick and Stephenson, 2007) to get more insight into the ongoing processes. In addition, it would be interesting to repeat our experiment with think aloud instructions in order to assess smokers' answers to the question warning labels, and to monitor the cognitive responses to all kind of warning labels.

Last, we selected the graphic warning labels concerning their deterrent content. Thus, graphic warning labels mainly depicted the same issues like the textual and question warning labels. However, there were some questions and statements, which were not covered by the graphics. Thus, the graphic warning labels might have been more fear or threat inducing than the textual warning labels condition because the latter ones also depicted issues like for instance, how to get help when trying to quit smoking. These issues might not be fear inducing, thus the graphic warning labels could have induced more fear than the textual warning labels. Nevertheless, both conditions involved two factors that might contribute to defensive responses: (1) the information provided on both, textual and graphic warning labels, derives from an external source which might not be as convincing as self-generated arguments (Mussweiler and Neumann, 2000); and (2) the information provided on both threatens the freedom to choose (Brehm and Sensenig, 1966; Grandpre et al., 2003). Nevertheless, there was no difference in risk perception between the graphic and the textual condition, but both differed significantly from the question and control condition. Thus, defensive responses might not have been elicited because of the threatening content but because of an external source providing the information. However, we cannot exactly conclude which of the two factors contributed to the differences; hence future research should distinguish between warning labels with and without fear inducing content to separate effects derived from fear, and effects derived from the fact that an external source provides anti-smoking arguments that

tell the smokers what they have to do and what they have to believe.

It may also be possible to use the present procedure of asking questions to increase risk perception when it comes to other health issues. However, the negative effects of a behavior have to be known in order to argue against it. For smoking, this seems to be the case, but this may be less true for other health damaging behaviors. Thus, the first step in health campaigns should always be to inform people about the consequences of health-related behavior. Only when this knowledge is well established, is it possible to introduce questions in warning labels as an additional factor that influences health-related risk perception and behavior.

Competing Interests

None declared.

Notes

1. In a pretest, 20 undergraduates from Saarland University, Germany, rated 32 graphic warning labels with regard to their deterrent impact on a nine-point Likert-scale ranging from 1 (not deterrent) up to 10 (very deterrent). Fifteen graphic warning labels with means between 6.20 and 9.75, average SD = 2.07, were chosen for the experiment.
2. In a second pretest, 20 undergraduates from Saarland University, Germany, rated 40 diseases in their relation to smoking on a seven-point-Likert-scale ranging from 1 (not caused by smoking) to 7 (caused by smoking). Six diseases with means between 5.57 and 6.95, average SD = 0.71, were chosen as smoking-related diseases (e.g. lung cancer, arterial occlusive disease).

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Tobacco Labelling & Packaging Toolkit

A guide to FCTC Article 11

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PREFACE

Tobacco packaging serves as a critical link to consumers, both for the tobacco industry and for governments seeking to convey the health risks of smoking. The brand imagery of the package is the foundation upon which all other marketing is built and plays an even greater role in jurisdictions where traditional forms of advertising, promotion, and sponsorship are restricted.

New international guidelines for tobacco packaging and labelling are being established under Article 11 of the World Health Organization's *Framework Convention on Tobacco Control* (FCTC)—the first international treaty devoted to public health. Article 11 will develop guidelines in three critical areas: 1) government-mandated health warnings, 2) labelling of tobacco constituents and emissions, and 3) the removal of misleading information from the package.

The implementation of these guidelines must be guided by evidence. The growing evidence base from countries that have already implemented comprehensive packaging and labelling regulations can be used to guide the elaboration and implementation of Article 11 guidelines for other FCTC parties.

This Toolkit was created to serve as a resource to support implementation of Article 11. It includes a review of evidence, as well as recommendations for designing health warnings on packages. Overall, the Toolkit is intended to simplify the process of developing effective labelling policies and to provide concrete resources for regulators, researchers, and tobacco control advocates.

EXECUTIVE SUMMARY

The evidence on effective packaging and labelling practices has grown rapidly over the past decade. Although much of this evidence has been collected in Western countries, there is a growing body of knowledge from different regions throughout the world, including low and middle-income countries. Despite regional differences in tobacco markets and labelling practices, a consistent pattern of findings has emerged:

The Package as a Marketing Tool

- Packages are the most direct and critical link to consumers.

- Tobacco packages serve as a "portable" advertisement and a "badge" product.

- Packages play a critical role in point-of-sale marketing.

- Packages are used to promote "below-the-line" marketing activities, sponsorships, and promotional activities.

- The industry continues to expand the boundaries of package design through innovations in printing technology, package shape, and plastic wrapping.

- The importance of the packages increases as other forms of marketing are restricted.

Health Warnings Labels

- Package health warnings are among the most prominent and cost-effective health communications available.

- Health warnings have high awareness and visibility among non-smokers and youth.

- Obscure text warnings have little impact.

- Large, prominent warnings located on the top of packages can increase health knowledge, motivation to quit, and cessation behaviour.

- Pictorial warnings are significantly more effective than text-only messages.

- Pictures are especially important for reaching low-literacy smokers and children.

- Messages that depict health risks in a vivid and emotionally arousing manner are most effective.

- "Graphic" information should be accompanied by supportive cessation information.

- There are <u>no</u> adverse effects in response to pictorial warnings.

- Health warnings must be regularly updated to maintain maximum impact.

- Large pictorial warnings are credible and have high levels of public support.

Emission & Constituent Labelling

- Emission numbers (i.e. tar and nicotine numbers) are <u>not</u> related to the amount of chemicals in a cigarette or the level of risk for a particular product.

- Emission numbers are highly <u>misleading</u> to consumers.

- Scientific bodies have called for the <u>removal</u> of emission numbers from packages.

- Numbers should be replaced with <u>descriptions</u> of emissions, constituents, and their health effects should be printed on packages.

Prohibitions on Misleading Information

- A central objective of tobacco industry marketing is to communicate deceptive differences in the risks of different brands.

- There are three primary packaging strategies that mislead smokers:

    1. Deceptive references to product design, such as the filtration properties.

    2. Misleading use of colour, symbols and brand imagery.

    3. Inherently misleading brand descriptors, such as *light*, *mild*, and *low tar*.

- More than 40 countries have prohibited the terms *light*, *mild*, and *low tar*; however, prohibitions must be broader to eliminate misleading substitutes, such as *smooth*.

- Removing misleading information will require restrictions on colour and brand imagery.

- "Plain" packaging is less appealing to youth, increases the effectiveness of health warnings, and is less likely to mislead smokers regarding the risks of their products.

EVIDENCE REVIEW

THE PACKAGE

Packaging is an important component in the overall marketing strategy of consumer goods.[1,2,3] Packaging helps to establish brand identity in competitive markets and serves as an effective form of promotion both at the point of purchase and while the product is being used.[4,5,6] Packaging is particularly important for consumer products such as cigarettes, which have a high degree of social visibility.[7,8] Unlike many other consumer products, cigarette packages are displayed each time the product is used and are often left in public view between uses.[9] As John Digianni, a former cigarette package designer noted: "A cigarette package is unique because the consumer carries it around with him all day…It's a part of a smoker's clothing, and when he saunters into a bar and plunks it down, he makes a statement about himself."[10] As a result, the package serves as a "badge" product, and an important form of advertising in its own right.[7]

Brown & Williamson (1985)

"… if you smoke, a cigarette pack is one of the few things you use regularly that makes a statement about you. A cigarette pack is the only thing you take out of your pocket 20 times a day and lay out for everyone to see. That's a lot different than buying your soap powder in generic packaging."[11]

British American Tobacco (1978)

"One of every two smokers is not able to distinguish in blind (masked) tests between similar cigarettes …for most smokers and the decisive group of new, younger smokers, the consumer's choice is dictated more by psychological, image factors than by relatively minor differences in smoking characteristics."[12]

Packaging and other forms of marketing

Cigarette packages also serve as an important link to other forms of tobacco advertising.[13] Package designs help to reinforce brand imagery that is communicated through other media, and play a central role in point of purchase marketing, which
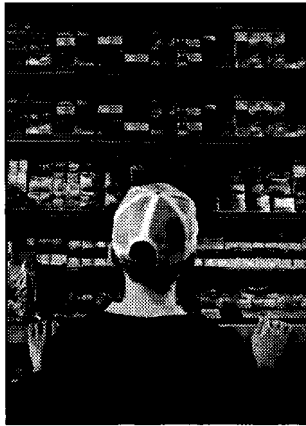
now accounts for a majority of the industry's promotional spending in Canada and the US.[14] Indeed, cigarette "power walls"—rows of cigarette packages prominently displayed behind retail counters—have been shown to be an effective form of marketing, particularly among youth and young adults.[15] Moreover, the marketing value of the cigarette package increases as other forms of marketing are restricted.[16,17] Internal documents from British American Tobacco also indicate that packages have been designed to compensate for restricted forms of advertising: "... given the consequences of a total ban on advertising, a pack should be designed to give the product visual impact as well as brand imagery. . . The pack itself can be designed so that it achieves more visual impact in the point of sale environment than its competitors."[18] Imperial Tobacco Canada, a wholly owned subsidiary of BAT and the

Du Maurier (Canada)

largest manufacturer in Canada, recently added a new twist to retail displays by re-packaging its leading du Maurier brand in octagon-shaped packages, with angled edges on the front and back of the package face (see right). Jeff Guiler, vice-president of marketing for Imperial Tobacco Canada, explained that the new shape was a way to attract consumer attention in a market with limited opportunities for advertising and promotion.
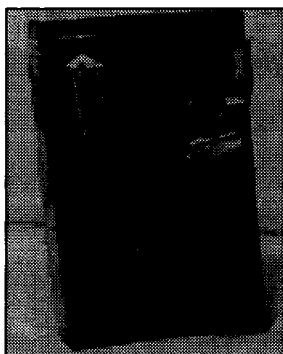
In particular, it was a way to reinforce the "prestige" of the du Maurier brand and to distinguish it from the growing number of discount brands in Canada. Guiler explained the implications of the new packages for the point-of-sale environment: "We decided that in order to leverage the full impact of the Signature Pack and overcome the fact that we are not allowed to do any kind of advertising, we needed to also redesign and refit our in-store displays to mirror the look of the pack." [19,20]

Beyond the retail environment, packages also help to increase the reach of "below the line" marketing activities.[21] For example, cigarette packages contain specific references to sponsorship and promotional activities, such as *Formula 1* racing series, concerts, and nightclub promotions. Overall, the cigarette package is the cornerstone of tobacco marketing strategy and poised to become even more important as, the following quote from a Phillip Morris executive indicates: "Our final communication vehicle with our smoker is the pack itself. In the absence of any other marketing messages, our packaging...is the sole communicator of our brand essence. Put another way—when you don't have anything else—our packaging is our marketing."[22]

Cigarette packaging and youth

Research conducted by the tobacco industry consistently demonstrates that the brand imagery portrayed on packages is particularly influential among youth and young adults—the period in which smoking behavior and brand preferences develop.[7,9,23,24,25] In many cases, initial brand preferences are based less on the sensory properties of product than on perceptions of the package and brand: "One of every two smokers is not able to distinguish in blind (masked) tests between similar cigarettes ...for most smokers and the decisive group of new, younger smokers, the consumer's choice is dictated more by psychological,
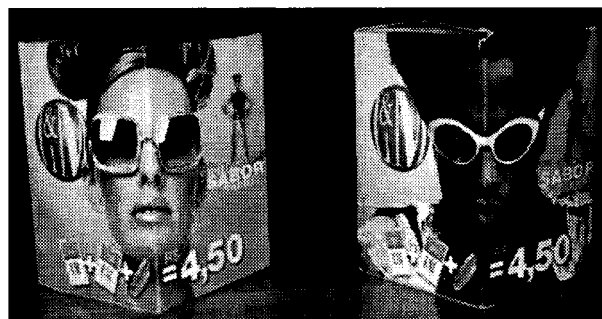
image factors than by relatively minor differences in smoking characteristics."[26] The brand imagery on cigarette packages is effective to the point that large majorities of

youth—including non-smoking youth—demonstrate high levels of recall for leading package designs.[27] This is particularly true when packages incorporate brand imagery that has broad appeal to younger audiences, such as the "Old Joe" cartoon image portrayed on *Camel* packages.[28]

Cigarette packaging and young women
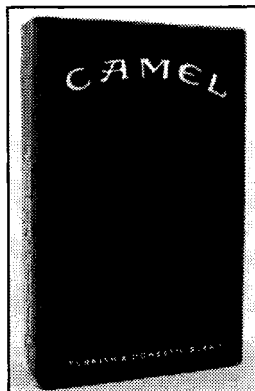
Package colours—especially pink and other pastels— are increasingly being used to target young women.[21] Leading brands, such as *Camel*, now offer cigarettes that come in female-oriented pink packages.[29] Other colours commonly used include purples, white, and light yellow.[30] These colours have been shown to suggest positive qualities such as freshness, cleanliness, purity, health, and intelligence.[1] Such colours and the use of other feminine symbols and images are widely acknowledged to portray smoking as feminine and stylish, in an attempt to make cigarettes more appealing to women, as well as to reduce perceived health risks.[33] Brand descriptors such as

"*slims*" are used to target young women by exploiting concerns about weight gain and the association between cigarette smoking and thinness.[31,32,33,34] Most recently, Phillip Morris released its newest attempt at targeting young women with "purse packs"—*Virginia Slims "Superslims"* that are contained in slim pink packages that are much narrower in diameter than regular packages, and easier to carry in one's purse.
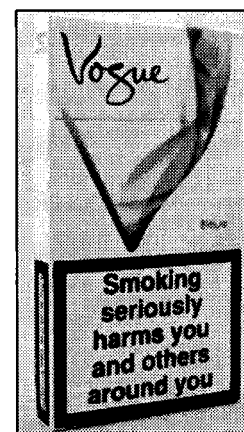
Packaging and other tobacco control measures

Packaging strategies can also be used to offset the impact of other tobacco control measures, such as increases in price and taxation. For example, internal tobacco industry documents indicate that packaging cigarettes into smaller, more affordable units (such as 10 cigarettes per package rather than 20) are an effective strategy for targeting price-sensitive youth.[23] Although legislation in many countries now prohibits the sale of cigarettes in units less than 20, innovations in the physical shape and construction of packages—such as BAT's "wallet packs" which open like a book and can be separated into two smaller packages—have been criticized as
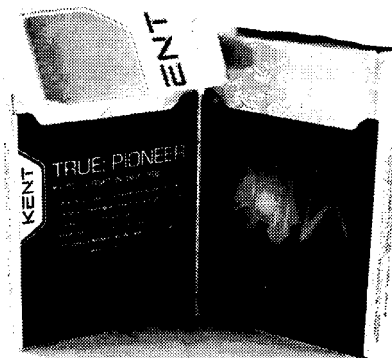
an attempt to circumvent these prohibitions.[35] BAT's wallet packs were recently banned in Australia after the federal court recently upheld an injunction against their sale. Tobacco companies have also explored packaging strategies to minimize the impact of health warnings, including changes in package design to make warnings less distinctive, as well as the sale of alternate cases and covers that obscure warnings.[36] Further innovation in tobacco packaging is on the horizon[37], as the following quotes indicate:

> "With the uptake of printed inner frame cards what we will increasingly see is the pack being viewed as a total opportunity for communications – from printed outer film and tear tape through to the inner frame and inner bundle. Each pack component will provide an integrated function as part of a carefully planned brand or information communications campaign." [38]

> "Advances in printing technology have enabled printing of on-pack imagery on the inner frame card, outer film and tear tape, and the incorporation of holograms, collectable art, metallic finishes, multi-fold stickers, photographs, and retro images in pack design. In the early 1900s, collectable cigarette cards were a major form of in-pack promotion. A contemporary return to the package as the primary source of advertising is apparent in the following examples."

In short, the package is a vital marketing channel for the tobacco industry and its value will continue to increase as more traditional forms of marketing are subject to increasing restrictions.
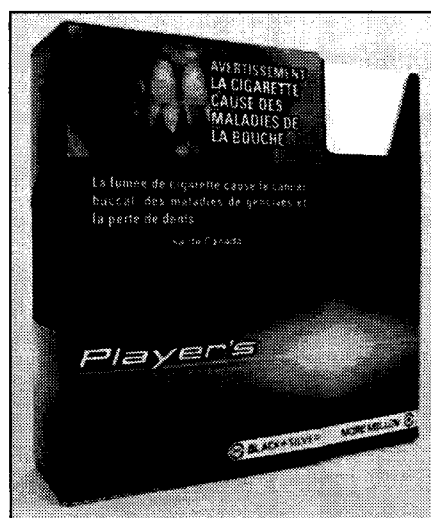
> **FCTC Article 11**
>
> *Each Party shall, within a period of three years after entry into force of this Convention for that Party, adopt and implement, in accordance with its national law, effective measures to ensure that:*
>
> *....Each unit packet and package of tobacco products and any outside packaging and labelling of such products also carry health warnings describing the harmful effects of tobacco use, and may include other appropriate messages. These warnings and messages: (i) shall be approved by the competent national authority; (ii) shall be rotating; (iii) shall be large, clear, visible and legible; (iv) should be 50% or more of the principal display areas but shall be no less than 30% of the principal display area; (v) may be in the form of or include pictures or pictograms.*

In addition to serving as a marketing vehicle for the tobacco industry, cigarette packages also provide governments with a direct means of communicating with smokers. Warning labels are primarily intended to communicate the health risks of smoking and to fulfill the government's responsibility as regulators to warn consumers about hazardous products.

At present, cigarette packages in the vast majority of countries carry a health warning.[39] However, the position, size, and general strength of these warnings vary considerably across jurisdictions. In the US, health warnings were first
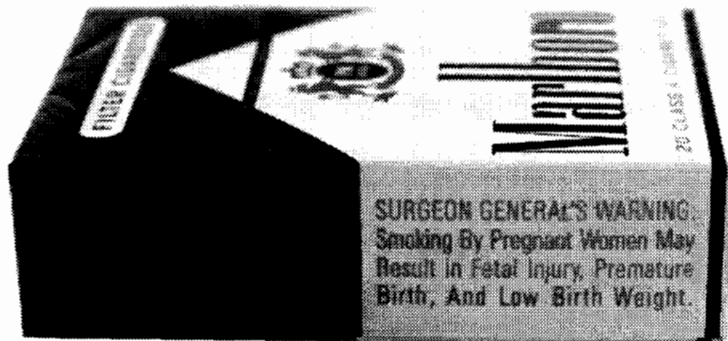
U.S. Health Warning

included on cigarette packages in 1966, and in advertisements in 1972. Since 1984, US cigarette packages have carried one of four government-mandated text warnings on the side panels of packages. In contrast, more than a dozen countries currently require large pictorial health warnings that cover at least 50% of the package, consistent with the recommendations in FCTC Article 11.

Cigarette packages are an excellent medium for communicating health information given their reach and frequency of exposure. Package health warnings are also unique among tobacco control initiatives in that they are delivered at the time of smoking and at the point of purchase. As a result, the vast majority of smokers report a general awareness of package health warnings and pack-a-day smokers are potentially exposed to the warnings over 7000 times per year. As a result, health warnings on cigarette packages are among the most prominent sources of health information: more smokers report getting information about the risks of smoking from packages than any other source except television.[40] Findings from Canada, Thailand, and elsewhere, indicate that considerable proportions of non-smokers also report awareness and knowledge of package health warnings.[41,42,43] As a result, health warnings are an extremely cost-effective public health intervention and have tremendous reach. However, the extent to which smokers read and think about, and act upon the warnings is highly dependent on their size, position, and design.

◉ **RESOURCE: Health warning pictures online**
An extensive list of picture-based health warnings that have been implemented throughout the world, as well as additional images used in test-marketing, can be reviewed at: www.tobaccolabels.org

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Size and Position of Health Warnings

Smokers are more likely to recall larger warnings, and have been found to equate the size of the warning with the magnitude of the risk.[42,44,45,46,47,48,49,50] One Canadian survey found that smokers judged warnings that covered 80% of the package to be most effective. For example, in studies where youth and adults are asked to rate the

effectiveness of different health warnings, the largest warnings are most likely to be rated as effective. [51,52,53] Smokers also report greater recall for warnings that appear on the front, compared to the side of packages.[44,47,49,50,51] For example, several studies indicate that the US text warnings on the side of packages demonstrate low levels of salience among smokers.[54,55,56,57] In a comparative study of students in Canada and the US carried out in 1995, at a time when Canadian packages carried text warnings on the front of packages, 83% of Canadian students mentioned health warnings in a recall test of cigarette packages, compared to only 7% of US students.[58] A Phillip Morris document also highlights the importance of positioning on the front of packages: "Government required warnings placed on the largest packaging panel, often called the front and/or back, are the biggest marketing threat to all of us in Asia..."[22] Features that distinguish the warning messages from the package design have also been found to increase the salience and recall of warnings.[59] Messages with contrasting colours, such as black lettering on a white background are the easiest to read, whereas the legibility of silver or gold text messages is comparatively poor.[47,60]

Literacy

The message content of text-based warnings must target an appropriate literacy level.[61] The current US warnings, for example, require a college reading level and may be inappropriate for youth and Americans with poor reading abilities.[62] This is particularly important considering that, in most countries, smokers report lower levels of education than the general public. Picture-based warnings may be particularly important in communicating health information to populations with lower literacy rates.[63,64] Preliminary evidence suggests that countries with pictorial warnings demonstrate fewer disparities in health knowledge across educational levels.[65]

Impact on Health Knowledge

Cigarette warnings labels have been demonstrated to have a significant impact on smokers' understanding of the risks of tobacco use. Several studies have shown that large text-based warnings are associated with increased perceptions of risk. Cross-sectional surveys conducted in Canada during the 1990's found

Hungary

that the majority of smokers reported that package warning labels are an important source of health information and have increased their awareness of the risks of smoking.[66,42] In Australia, Borland[67] found that, relative to non-smokers, smokers demonstrated an increase in their knowledge of the main constituents of tobacco smoke and identified significantly more disease groups following the introduction of new Australian warning labels in 1995. Several studies have evaluated enhancement of text warnings in European Union (EU) to a minimum of 30% of the principle display area of the package. First, a study of Spanish university students concluded that text warnings based upon the EU directive significantly increased perceptions of risk.[68] These findings were consistent with results from a series of studies conducted with a representative sample of smokers in the UK, France, Scotland, and Ireland on the effects of similar text warnings that were introduced in 2003 in compliance with the EU directive. [69,70] Collectively these studies indicate that smokers' awareness of the warnings increased following the new warnings and considerable proportions of smokers report thinking about health risks and quitting smoking as a result of the large text warnings.

The use of Pictures and Sybmols in Health Communications

A wide variety of research has clearly demonstrated the effectiveness of using pictures and imagery in health communications.[71,72,73,74,75] This research has demonstrated that warnings with pictures are significantly more likely to draw attention and result in greater information processing, and improve memory for the accompanying text. Picture warnings also encourage individuals to imagine health consequences and are also more likely to be accessed when an individual is making relevant judgments and decisions. As a result, the use of pictorial symbols is a common and effective feature of health warnings for a wide variety of consumer products.[76,77,78,79,80,81,82]

Pictures and Sybmols in Tobacco Warning Labels

Experimental research on cigarette warnings has also found that picture-based warnings are more likely to be rated as effective versus text-only warnings both as a

deterrent for new smokers and a means to increase cessation among current smokers.[83,84,103]

Extensive focus group testing and market-research commissioned by government health agencies also underscores the importance of using pictures in package health warnings. This research consistently demonstrates that health warnings with pictures are rated by smokers and non-smokers as more effective and associated with greater impact and memory for health risks than text-only warnings. The following includes summary statements from several prominent sources.
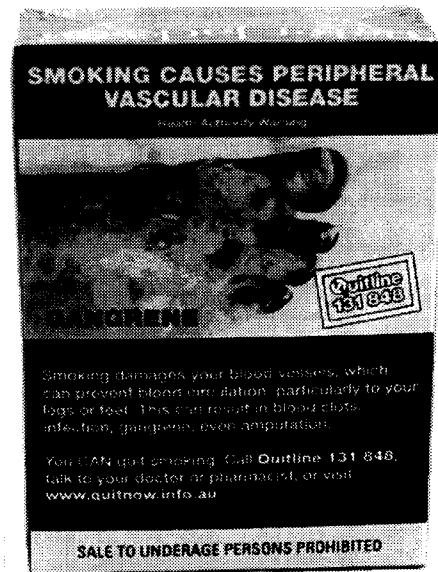
Summary of Health Canada Research Conducted Prior to 2000

Participants felt that the new larger health warning messages, featuring colour photographs, were a definite improvement over the current warning messages. Teenagers were particularly impressed with the use of pictures and the larger size of the messages that allow for the dissemination of more information.
                                        Overall Responses to New Warning Messages,

p.5[85]

Summary of Research Commissioned by the Australian Department of Health

"The graphic packs were more informative about health effects and more effective in general in conveying health information regarding the contents of cigarettes and cigarette smoke than were the "text only" alternatives. They were also more likely to elicit an emotional response from smokers. They will generate controversy and discussion about smoking and its health and social effects. The graphic packs are more likely to: create impact; attract attention; be confronting and difficult to ignore; make it more difficult for smokers to deflect the health message. Overall, the "text only" packs were not considered as impactful or as effective in conveying the potential negative health consequences of smoking as the graphic pack alternatives."
                                        Executive Summary, p.5[86]

Summary of Research Commissioned by Health Canada Since 2000

"It also appears that messages have to be credible and supported by facts and visual depictions wherever possible."

"Other graphic approaches showing dramatic negative health effects, although not necessarily liked, were effective in garnering notice among a number of participants."

Executive Summary, p.3[87]

"The picture was generally the first thing people looked at and related to. It determined the strength of the warning's emotional impact and noticeability. For many participants, the picture played the key role in understanding the message, and tended to override the meaning conveyed by the words in the headline. Therefore, those warnings with a clear, simple and effective headline to support or complement the emotionally strong visual were the ones that consistently generated positive and almost enthusiastic feedback from participants."

Executive Summary, p.4[88]

Summary of Research Commissioned by the New Zealand Ministry of Health

"All experience and evidence suggests that a combination of visual and text provides the best possible communication; the visual element to attract attention and telegraph a strong message, the text to expand and provide information."

Summary, p.14[89]

"Respondents consistently mentioned visuals as being the crucial element-i.e. clear pictorial evidence of the consequences of smoking or the potential gains of quitting."

Summary, p.6[90]

"By way of a high-level summary of findings, the following key consideration emerged from the research:
-Pictorial messages are likely to have significantly more impact than text-only message.
-The larger the pictorial message, the greater its impact."

Summary p.6[91]

Since 2000, when the first pictorial warnings were introduced in Canada, a series of population-based surveys have compared the effectiveness between text and pictorial warnings. These findings are consistent with both the experimental and government commissioned research: graphic warnings are more likely to be noticed and read by smokers, are associated with stronger beliefs about the health risks of smoking as well as increased motivation to quit smoking.[69,84,87,88,90,91,92,93,94,95,96,97,98,99,100,101,102]

Picture warnings appear to be especially effective among youth: more than 90% of Canadian youth agree that picture warnings on Canadian packages have provided them with important information about the health effects of smoking cigarettes, are accurate, and make smoking seem less attractive.[42] Other national surveys of Canadian youth suggest similar levels of support and self-reported impact.[41] A recent longitudinal evaluation of pictorial warnings among Australian school children found that students were more likely to read, attend to, think about, and talk about health warnings after the pictorial warnings were implemented in 2006.[101] In addition, experimental and established smokers were more likely to think about quitting and forge cigarettes, while intention to smoke was lower among those students who had talked about the warning labels and had forgone cigarettes. Recent experimental research conducted among youth in Greece is consistent with these findings.[103] In recognition of this evidence, the Elaborated Guidelines of FCTC Article 11 state that:

FCTC Article 11 Elaborated Guidelines

"Evidence shows that health warnings and messages that contain both pictures and text are far more effective than those that are text-only. They also have the added benefit of potentially reaching people with low levels of literacy and those who cannot read the language(s) in which the text of the health warning or message is written. Parties should mandate culturally appropriate pictures or pictograms, in full colour, in their packaging and labelling requirements."[104]

"Graphic' picture and the use of fear arousing information

Pictorial warnings that contain graphic images of health effects have been criticized on the grounds that threatening information may cause defensive reactions among smokers that lessen the likelihood of quitting.[105] Graphic warning labels showing "shocking" pictures of health effects do indeed cause strong emotional reactions among a considerable proportion of smokers and non-smokers.[98,106] However, strong emotional reactions are associated with
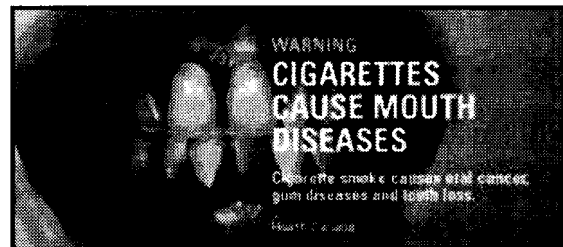
Canada

increases in the effectiveness of warnings.[98] Indeed, there is no evidence that graphic warnings labels decrease the effectiveness of the warnings in terms of intentions to quit, thinking about health risks, or engaging in cessation behaviour. For example, a recent experimental study compared picture warnings that showed graphic depictions of disease (or "loss-framed" message) versus pictorial warnings that emphasized the positive aspects of abstaining from smoking (or "gain-framed" messages). The results indicated that adolescents had more favorable attitudes toward the loss-framed warnings and perceived them as more effective than the gain-framed warnings. Further, smokers exposed to the loss-framed version featuring decaying teeth had significantly lower intentions to smoke in the future.[107]

It has also been suggested that smokers will simply avoid warnings that are too strong and will "tune out" the health messages. Although several studies indicate that a considerable portion of smokers make some attempt to avoid graphic pictorial health warnings by covering or hiding the warnings and using another case, these examples of

fear control behaviour do not necessarily reflect an adverse outcome or inherent weakness of package warnings. Research has demonstrated that avoidant behaviours and attempts at thought suppression often have the opposite effect of increasing the presence of the unwanted

Singapore

23

thoughts.[108] One study found that smokers who attempted to avoid the warning were nevertheless no less likely to see the warnings, think about them, or engage in cessation behaviour at 3-month follow-up.[98] Preliminary findings from a longitudinal study of the pictorial warnings in Australia also demonstrate a positive association between "avoidant behaviour" and self-reported measures of effectiveness, such as foregoing a cigarette and increases in motivation to quit smoking as a result of the warnings.[109] In the context of the warning labels, avoidant behaviour might be more reasonably interpreted as a measure of effectiveness. Indeed, if the warnings were ineffective in communicating the threatening consequences of smoking there would be no reason to avoid them.

In fact, research in the field of health communication indicates that messages with emotionally arousing content are more likely to be noticed and processed by smokers.[110] The most consistent finding from this literature is that fear appeals are effective when paired with strong efficacy messages for a specific outcome (i.e. quitting smoking). A recent meta-analysis of the literature on public health communications concluded that 'strong fear appeals and high-efficacy messages produce the greatest behavior change', and found no evidence of any adverse or 'boomerang' effects for strong fear appeals.[110] Graphic warnings in Canada, Australia, Singapore, Brazil, and other countries are
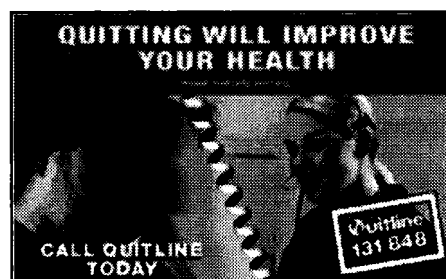
Australia

Belgium

entirely consistent with this literature: in addition to information on health risks, they include messages designed to increase self-efficacy for quitting. These messages include both general messages of support, as well as concrete information on ways to quit smoking and specific sources of help, including website addresses and toll-free "quitline" numbers.

The effectiveness of graphic fear-inducing images is supported by surveys and focus groups with smokers. For example, an extensive public consultation was conducted by the UK Department of Health that received more than 20,000 responses. The highest rated warnings were generally those that included the "hardest hitting" messages and images, including graphic pictures of the health effects of smoking (see right).[111] Research conducted on behalf of the Australian, New Zealand, and Canadian governments yielded similar results:
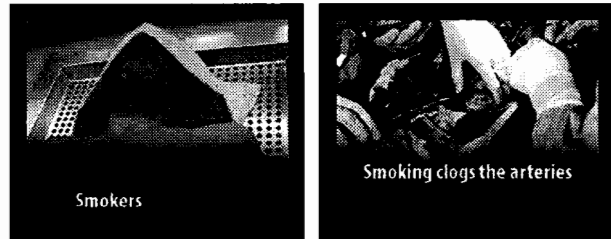
United Kingdom

"Participants in all groups consistently expected or wanted to be shocked by HWMs, or emotionally affected in some way. Even if the feelings generated were unpleasant ones to tolerate, such as disgust, fear, sadness or worry, the emotional impact of a warning appeared to predict its ability to inform and/or motivate thoughts of quitting. HWMs which worked on emotions rather than on knowledge or beliefs were often acknowledged as effective and noticeable, and actually motivated thinking. When a strong emotion generated by a HWM was supported by factual information, that was the best combination possible."

Overview of Findings, p.3[88]

"Most participants were moved by the dramatic and scary pictures and messages, such as the woman smoking through a hole in her throat, the sick baby, the cemetery with grieving loved ones, and warnings that depicted the physical and health consequences of smoking, such as the diseased mouth."

Overall Responses to New Warning Messages, p.5[85]

Health warnings and cessation behaviour

The extent to which health warnings lead to changes in smoking behaviour is difficult to ascertain within the context of population-based data. However, significant proportions of adult and youth smokers report that large comprehensive warnings have reduced their consumption levels, increased their likelihood of quitting, increased their motivation to quit, and increased the likelihood of remaining abstinent following a quit attempt.[42,96,97,98, 112,113,114,115,116,117,118,119,120] In at least three studies, longitudinal studies have demonstrated an association between reading and thinking about health warnings and subsequent cessation behaviour.[97,101,102] Increases in the use of cessation services have also been associated with health warnings. Research conducted in the UK, the Netherlands, Australia, New Zealand, and Brazil has examined changes in the usage of national telephone "helplines" after the contact information was included in package health warnings. Each of these studies reported significant increases in call volumes. [118,121,122,123,124] For example, calls to the tollfree smoking cessation helpline in the Netherlands increased more than 3.5 times after the number was printed on the back of one of 14 package warnings.[122] Therefore, while it is not possible to precisely quantify the impact of health warnings on smoking prevalence or behaviour, all of the evidence conducted to date suggests that health warnings can promote cessation behaviour and that larger pictorial warnings are most effective in doing so.

Brand Appeal

Prominent health warnings that cover a significant proportion of the package also have the potential to undermine a brand's appeal and the impact of package displays at retail outlets.[116,125,126,127,128] One recent study found that including graphic pictures compared to text-only warnings lowered the appeal of non-combustible products, nicotine lozenges, and cigarettes with modified designs.[129] A Quebec Superior Court judge remarked upon this phenomenon in a ruling regarding the industry's challenge to pictorial warnings in Canada: "Warnings are effective and undermine tobacco companies' efforts to use cigarette packages as badges associated with a lifestyle."[130]

Chile

Credibility & Public Support

Research indicates that smokers report graphic warnings to be a credible source of information, particularly when attributed to a well respected Department of Health or a well respected non-governmental authority, such as a cancer society.[90,150,131] The levels of credibility do not appear to be associated with the type or design of warning labels: like text-based warnings, smokers report high levels of believability for graphic picture-based warnings.
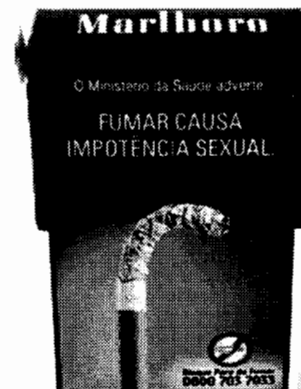
Brazil

Uruguay

Several studies also report high levels of public support for graphic pictorial warnings.[98,132,133] For example, in Canada more than 90% of youth agreed that picture warnings on Canadian packages have provided them with important information about the health effects of smoking cigarettes, are accurate, and make smoking seem less attractive.[42] In Brazil, a national survey indicated that 76% of those interviewed approved of the measure, including 73% of smokers.[118] Two years after the introduction of large pictorial warnings in Uruguay, only 8% of adult smokers reported they would prefer less health information to appear on packages, whereas 62% reported they would like more health information on packages.[134] Similar levels of popular support have been observed following the introduction of pictorial warnings in Canada and Thailand.[97,135] Although tobacco companies have suggested that pictorial warnings "harass" smokers, research suggests that, overall, smokers welcome more health information on their packages, including information that presents the health consequences of smoking in a vivid, arousing manner.

"Wear-out" and impact over time

It is widely accepted that the salience of advertising and health communications is typically greatest upon initial exposure.[136,137] For example, a recent study found that new text-based warnings introduced in the United Kingdom in 2003 were considerably more likely to be noticed than Australian text-based warnings which were only slightly smaller, but had been in place for more than eight years at the time of the survey.[96] The frequency with which smokers read and attend to warnings has been shown to lessen over time as smokers become desensitized to the warnings.[138,139,140] As a result, health warnings must be regularly updated to maintain their maximum impact over time.

Government Regulation & Industry opposition

The tobacco industry has vigorously opposed comprehensive tobacco labelling policies, especially in the case of pictorial labels.[141] For example, as Alechnowicz and Chapman[142] have noted, in 1995, package warnings were identified by British American Tobacco as one of the key issues facing the company. Protecting the pack design and "neutralizing" the controversy over pack warning labels were among the priorities listed in the document.[143] The same document goes on to state that, "pictorial warnings, and those occupying a major pack face or faces (front and back) or a disproportionately large area of advertising space, should be restricted, as should moves to plain or generic packs. Every effort should be made to protect the integrity of the company's packs and trade marks".[143]

Thailand

In public, tobacco manufacturers have argued that large comprehensive warnings are not only unnecessary, but are less effective than more obscure text messages.[141] For example, Martin Broughton, the former Chairman of BAT recently stated that: "The growing use of graphic image health warnings ...can offend and harass consumers- yet

in fact give them no more information than print warnings."[144] Tobacco manufacturers have also argued that comprehensive warnings constituent an unreasonable and illegal expropriation of cigarette packaging.[7]

To date, courts of law have disagreed. For example, in response to a legal challenge of the Canadian Tobacco Act, the court found that the tobacco companies' right to advertise their products could not be given the same legitimacy as the federal government's duty to protect public health. In short, the courts have ruled that even graphic warnings are warranted considering the societal costs of smoking.

Alternative tobacco products

Labelling requirements for manufactured cigarettes are more advanced than for other tobacco products. In many jurisdictions, tobacco products such as cigars and smokeless products are subject to different regulations and often carry a different set of health warnings or no warning at all. There is a need for research to examine issues such as alternative packaging sizes, as well as the extent to which alternative tobacco products require unique message content to reflect differences in health effects and patterns of use.[145] In addition, in many jurisdictions tobacco products are sold without any manufactured packaging. This practice will inevitably reduce the impact of comprehensive labelling policies. For some products sold without packaging, such as manufactured cigarettes that are sold individually, it may be possible to print health warnings directly on the cigarette itself. For other products sold without packaging, such as "loose" or "fine cut" tobacco, this may be impossible given the nature of the product. Given the lack of information in this area, research on health warnings for "alternative" tobacco products should be regarded as a priority.

> **FCTC Article 11:**
>
> *Each unit packet and package of tobacco products and any outside packaging and labelling of such products shall, in addition to the warnings specified in paragraph 1(b) of this Article, contain information on relevant constituents and emissions of tobacco products as defined by national authorities.*

Disclosure of constituents and emissions has presented a unique challenge to regulators. Cigarette smoke contains approximately 4,000 chemicals, including over 60 carcinogens and toxins such as polonium 210, benzene, and arsenic.[146] Although there is general agreement that cigarette packages should include some information on these chemicals, regulators continue to struggle with how best to communicate this information in a feasible and meaningful way to consumers.

Indeed, the primary rationale given for the disclosure of emissions and constituents is to inform consumers about the contents of tobacco products; however, the benefits of communicating this information to consumers are by no means certain.

At present, national authorities have taken much different approaches to labelling constituents and emissions. The traditional regulatory practice in many jurisdictions has

China

been to require manufacturers to print levels for three emissions in the mainstream smoke: tar, nicotine, and carbon monoxide (CO). These numbers are typically printed on the side of packages. In fact, communicating emissions numbers to consumers was originally an industry practice. Tobacco manufacturers have communicated tar and

nicotine numbers directly to smokers ever since the health risks of smoking became publicly known.[147] These early forms of "product disclosure" were motivated less by consumer protection than by a marketing strategy intended to capitalize upon widespread misperceptions of "lower tar" products. Despite early objections by regulatory authorities such as the U.S. Federal Trade Commission, this industry practice was adopted by regulatory communities throughout the world.[148]

Cigarette emissions

Tar, nicotine, and carbon monoxide emission numbers are misleading. They represent neither the amount of chemicals present in the cigarette (i.e. tobacco "constituents"), nor the amounts actually ingested by human smokers. This is because the emission numbers are determined by a machine that "smokes" cigarettes according to a fixed puffing regime. This machine method does not predict the amount of smoke inhaled by individual consumers or account for design elements such as "filter ventilation"—tiny holes poked in the filter that yield low emission levels under machine smoking, but much higher levels under human smoking.[149] As a result, there is no association between the machine-generated numbers printed on packages and the health risk of different brands. In short, the underlying premise for communicating tar and nicotine numbers directly to consumers—that "low tar" cigarettes are less harmful—has since been rejected.
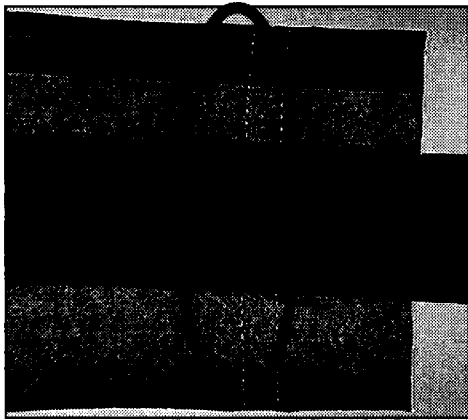
Filter ventilation

European Union

Although the scientific consensus on tar and nicotine emissions has evolved, the practice of communicating these numbers to consumers remains widespread: not only have manufacturers continued to communicate tar and nicotine levels directly to consumers via advertising, but many regulators continue to do so

through packaging and labelling regulations. Research has repeatedly shown that although many smokers are not able to recall the specific tar level of their brand, a substantial proportion nevertheless equate lower numbers with a reduction in exposure and risk, and many use these numbers to guide their choice of brands.[150,151,152, 153,154,155] Recent findings suggest that smokers even in the most affluent and educated countries continue to hold false beliefs about emission numbers:

o 75% of smokers from Australia, Canada, the U.S., and the UK recently reported that the tar numbers on packs are related to exposure.[156]

o Among smokers in the same study who believe that some brands are less harmful than others, 81% believe that the tar and nicotine levels indicate the brands that are less harmful.[156]

o When shown emission labels on two cigarette brands from the European Union, 92% of smokers recently reported that the 4mg product would deliver less tar than the 10mg product, and 90% reported that they would buy the 4mg product if they were trying to reduce the risks to their health.[100]

o These findings are consistent with the ways in which smokers have been shown to perceive emission numbers when conveyed through advertising.[147]

Overall, printing emission numbers on packages reinforces the tobacco industry's deceptive marketing campaign and the false belief that low tar cigarettes are less hazardous.

In many cases, manufacturers voluntary print emission levels on packages even in the absence of regulation. For example, in the United States there are no requirements to print emission levels on packages. However, a number of manufacturers do so voluntarily, albeit in a highly selective fashion. In 2004 and 2005, tar levels were printed on more than 90% of U.S. brands with less than 3mg of tar, compared to fewer than 2% of brands with 8-11mg of tar.[157] Similar practices have occurred in other jurisdictions, such as Brazil, where regulators have removed the requirement to print numbers, but have not prohibited manufactures from doing so.

In light of these findings, some jurisdictions have supplemented the emission numbers with additional emission information. In 2000, Canada increased the list of emissions that must be reported and added a second set of emission numbers generated under the "Health Canada" method, a more intensive machine smoking method (see right). This emission testing method is no better at predicting exposure or risk than the lower set of numbers.[158]


Canada

Subsequent research conducted on behalf of Health Canada found that 4 out of 5 smokers did not understand the emission information; nevertheless, more than half reported that they would use these numbers "to find a less harmful brand".[150] More recent research found that Canadian smokers and non-smokers rated the emission information on Canadian packs as significantly more "informative" and "useful" than the emission information on EU and Australian packs; however, the Canadian emission information was also rated as the "most difficult to understand," and the vast majority of smokers reported that the numbers could be used to identify less harmful brands.[100]

Overall, consumer misperceptions are not simply due to flaws in a particular testing method and the actual value of the numbers, but the practice of assigning different brands different numbers. Changing the metric of cigarette emissions by using more intensive testing methods provides little insurance against the likelihood that consumers will interpret brands with lower numbers as lower risk. If the scientific consensus is that there are no measurable differences in risk between conventional cigarette brands, regulators should not communicate numerical toxicant levels that suggest otherwise. Indeed, the "Elaborated Guidelines" for FCTC Article 11 state: "Parties should prohibit the display of figures for emission yields, such as tar, nicotine and carbon monoxide, on packaging and labelling, including when used as part of a brand name or trademark."[104]

Non-numerical emission labelling

Overall, there is no evidence that quantitative emissions constitute effective consumer information and leading scientific bodies have called for the removal of emission numbers from packages.[159] To date, at least five countries have removed emission information from packages and

Brazil

replaced it with descriptive information about toxic constituents and their effects on health. Preliminary research suggests that this information is more meaningful to
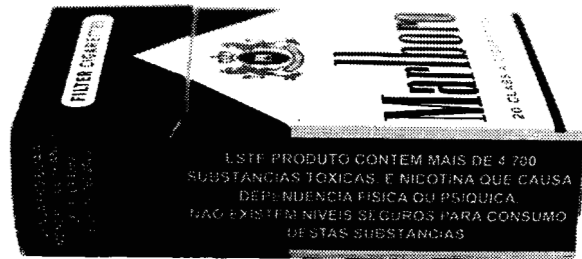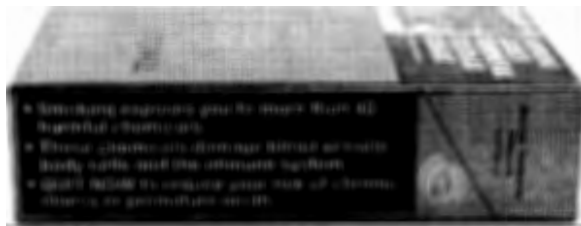
Australia

consumers and less likely to result in misperceptions about the relative risk of different cigarette brands.[100,160] Further work is required to examine what types of descriptive product information are most useful to consumers. For example, it remains unclear whether consumers would be best served by a long list of toxic chemicals, a subset of the most hazardous chemicals, or perhaps the most recognisable toxicants, such as arsenic and benzene. The extent to which additives or design features (such as filter ventilation) might serve as effective consumer messaging is also unclear. See Chapter 3 of this Toolkit for recommendations on designing toxic emission messages, including examples.

Thailand

Uruguay

PLAIN PACKAGING AND PROHIBITIONS ON MISLEADING INFORMATION

> **FCTC Article 11:**
> *Each Party shall, within a period of three years after entry into force of this Convention for that Party, adopt and implement, in accordance with its national law, effective measures to ensure that:*
> *....tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as "low tar", "light", "ultra-light", or "mild."*

Tobacco companies have made extensive use of cigarette packages to convey information regarding the risks of cigarettes.* Prior to the 1950's, tobacco packages rarely included information about tar levels or other information that might cause smokers to reflect upon health risks. However, following the publication of the first Surgeon General's report on the health risks of smoking in 1964, tobacco companies have sought to actively reassure consumers about the potential risks of their products. A central feature of this marketing strategy has been to promote differences in the relative risk of brands and to integrate this marketing strategy into the design of products themselves, largely through the promise of improved filtration and lower emissions. Nicotine-addicted consumers embraced these brands as a welcome alternative to quitting, as well as a means of easing the guilt and cognitive dissonance from smoking.[147]

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* Note that several quotes and sources in this section are drawn from a recent review prepare by Freeman, Chapman, & Rimmer[24]

The package has served as an essential medium for executing this marketing campaign. In general, tobacco companies have relied upon implicit means to promote differences in risk, rather than overt health claims on the package.[147] This has been accomplished using a number of packaging elements, including references to product design, the use of misleading descriptors, as well as the use of colours and symbols.

References to product design

Products that are positioned as "low yield" brands often carry images or references to product design on the package.[161] References to filtration are among the oldest and most common examples of this strategy. For more than 50 years, tobacco companies have communicated filter properties to consumers as tangible evidence of emissions reduction and lower risks. Indeed, the rise of filtered cigarettes in the U.S. paralleled the rise in health concerns among consumers.[146] From Kent's *Micronite* filter, to Barclay's *ACTRON* filter, to the charcoal filters currently being test marketed in Marlboro Ultra Smooth—whatever the filtration properties of these designs may be, they reassure smokers when displayed on the package.[162] As Myron Johnston and W.L. Dunn of Philip Morris stated in 1966, "the illusion of filtration is as important as the fact of filtration."[163]

The images on the right provide a contemporary example of this packaging strategy from China, where two leading brands feature images of high-tech filters and references to "laser holes," "active carbon particles," and "colour cellulose particles." Packages with pictures and references to special cigarette filters such as these are rated by a majority of smokers as having less tar and lower health risk.[100] These references to product design and chemical profile on the package are

China

meaningless in terms of actual risk; however, as internal tobacco industry documents indicate, the illusion of improved filtration and technology falsely reassures consumers.[164]

Brand descriptors

Tobacco manufacturers incorporate a variety of common terms into the names of their cigarette brands. Words such as *light* and *mild* are ostensibly used to denote flavour and taste; however, *light* and *mild* brands are often promoted as "healthier" products and have been closely integrated with product design in order to maximize their impact.[9,147,149,161] Brands with descriptors such as *light* and *mild* are typically applied to brands with higher levels of filter ventilation that generate lower machine levels of tar. Not only does filter ventilation dilute cigarette smoke to produce deceptively low emission numbers under machine testing, but it also produces "lighter" tasting smoke and other sensory properties that reinforce the misleading descriptors and images on packages. Indeed, smokers associate the "flavour" and harshness of the smoke with the level of risk.[165] The synergistic but subtle effect of brand descriptors, low emission numbers, and the "lighter" tasting smoke has proven extremely effective in promoting misleading perceptions off risk to smokers.[149,166,167,168,169,170,171] For example these deadly misperceptions have the potential to forestall quitting among many "health concerned" smokers and persist to this day among a considerable proportion of smokers.[149,172] For example, more than 50% of Chinese smokers believe that brands labelled as *light* are less harmful than regular cigarettes.[173]

Words in the name of the brand are persuasive to the point that they can influence sensory properties of smoking a cigarette. One study found that even the name of a cigarette brand is enough to alter people's beliefs about the quality and attractiveness of cigarettes. When Friedman and Dipple had 200 men and women smoke identical cigarettes but told them the brand was called either "April" (a feminine name) or "Frontiersman" (a masculine name), women rated the cigarettes named "April" more favourably, whereas the men rated the cigarettes they believed were named "Frontiersman" more favourably.[174]

Numbers are also used in the name of cigarette brands to distinguish between different varieties. These numbers often correspond to the machine levels of tar emissions.[147] As explained in the previous section, there is extensive research showing that consumers perceive lower tar products as "healthier" than regular or higher tar products. When shown packages with different numbers in the brand name, as many

Japan

as 80% of smokers report that the brand with the lower number would deliver less tar and may lower risk.[100] The Elaborated Guidelines under Article 11, clearly state that these numbers should be prohibited from packages.[104]

Canada

Prohibitions on misleading brand descriptors

To date, at least 44 countries have prohibited the use of the words *light*, *mild*, and *low tar* on packaging, including 27 countries from the European Union.[175] Although *light*, *mild*, and *low tar* are the most notable examples of misleading brand descriptors, they are by no means the only ones. Indeed, a wide variety of other descriptors have been designed to reinforce the same false beliefs and perceptions. For example, the term *smooth* has been used as a replacement for *light* and *mild* in a number of jurisdictions with prohibitions.[176] Other common substitutes for *light* and *mild* include the names of colours, such as *silver* and *blue*, which capitalize on the perceptions of these colours as being "lighter". These replacement words have the same misleading effect as *light* and *mild*: a recent study found that more than 70% of smokers reported that packages with words such as *smooth* and *silver* would have lower health risks than *regular* and *full flavour* brands.[100] In addition, recent research conducted in the UK found that 54% of children surveyed identified *Mayfair Smooth* as less harmful than *Mayfair King Size*, similar to the proportion

Canada

that believed that brands described as "light" brand was less harmful (59%).[171]

Therefore, although the removal of *light*, *mild*, and *low tar* terms represent an important first step in removing misleading product information from packages, recent research in Australia and the UK, where these terms have been prohibited, suggests only modest benefits, in terms of reducing false beliefs about the risks of different cigarette brands.[177] The marginal impact of removing the words *light*, *mild*, and *low tar* is likely due to greater colour segmentation, the substitution of other misleading terms such as *smooth*, and the tar and nicotine numbers on UK packages.

"Plain" packaging and the impact of colour and brand imagery

Colour, symbols, and imagery

Colour is routinely used in package design to shape consumer perceptions of risk.[7,9] Research has shown that consumers associate the "lightness" and "strength" of a brand with different colours. For example, blue tones are perceived as "lighter" than red, while products in grey and white packages are perceived to be the "lightest." Recent research in the UK found that cigarettes in a light grey package were rated by four out of ten smokers as less harmful than cigarettes in an otherwise identical red pack. Similar levels of false beliefs were observed among children in the same study. In the same study, different shades of the same colour, as well as the proportion of white space on the package, can also be used to manipulate perceptions of the strength and acceptability of the product itself. The following quote from a Philip Morris researcher describes this phenomenon:[9]

> "Lower delivery products tend to be featured in blue packs. Indeed, as one moves down the delivery sector, then the closer to white a pack tends to become. This is because white is generally held to convey a clean healthy association."[178]

Example of colour segmentation with brand varieties (Gauloise—France)
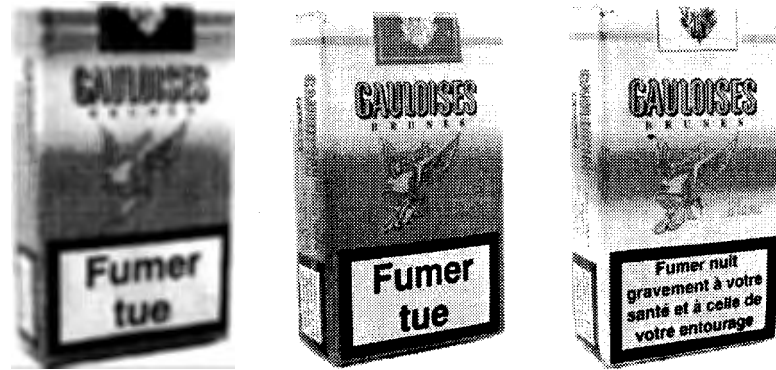
Colour can be used to convey other properties of cigarettes. For example, silver and gold are used to convey status and prestige, particularly for "premium" brands.[7] Red packages and logos convey excitement, strength, wealth, and power.[179,180]

In addition to the use of colour, packaging often includes imagery and symbols with strong associations with health, including images of nature scenes, physical activity, and sport.[7,147]
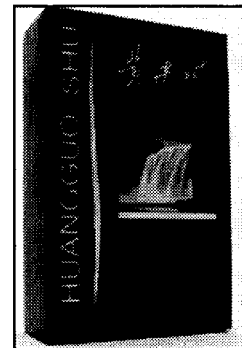
China

As one indication of the power of colour and imagery, the Canadian subsidiary of Philip Morris recently introduced the U.S. Marlboro cigarette in the Canadian market without the Marlboro name because the trademark is owned by a competitor. This product carries no identifiable name on the package (see below). This speaks not only to the familiarity of the Marlboro chevron logo, but also to how colour alone can be used to distinguish between brand varieties and emission levels.
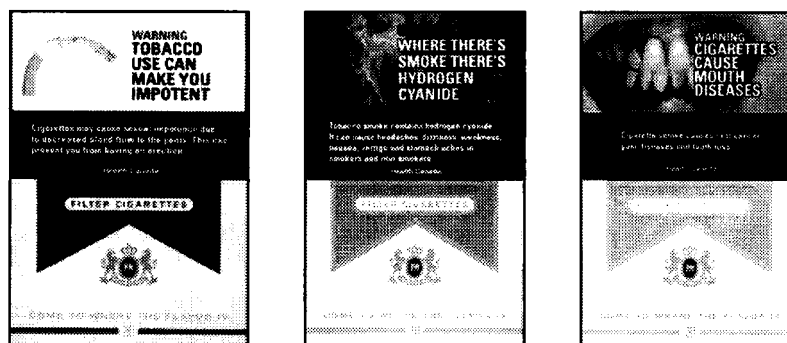
"Rooftop" Brand Without Identifiable Name on Package (Canada)

Research conducted with adult smokers in the UK, where packs carry the name Marlboro, but use only colour to distinguish between different varieties, found significant levels of false beliefs associated with these brands. Compared to Marlboro packs with a red logo, Marlboro packs with a gold logo were rated as lower health risk by 53% and easier to quit by 31% of adult smokers.[171]

A number of studies have shown that the colour and design of the package are effective to the point where they can affect sensory perceptions of a cigarette, a process known as "sensory transfer." Imperial Tobacco Canada Ltd, a subsidiary of British American Tobacco, summarized extensive research on "brand imagery" that demonstrates how the design of the package alone can affect sensory perceptions of the product.[181] The following provides a description of similar research conducted by Philip Morris:

> Philip Morris marketing research department compared smokers' responses to cigarette packages in a blue and red pack. Despite the cigarettes being identical in composition, smokers appraised the cigarettes in the blue pack as "too mild" and "not easy drawing". Others felt that the cigarettes in the red pack were "too strong" and "harsher".[9]

Overall, the colour and brand imagery of a brand has a significant impact upon product perceptions. As Imperial Tobacco Ltd's Vice President of marketing noted: "it's very difficult for people to discriminate blind-tested. Put it in a package and put a name on it, then it has a lot of product characteristics."[182]

Plain packaging
Plain packaging has been proposed as a way to address the impact of colour and other elements of brand imagery on packages. Plain packaging would standardize the appearance of cigarette packages by requiring the removal of all brand imagery, including corporate logos and trademarks.[183] Packages would display a standard background colour and manufacturers would be permitted only to print the brand

name in a mandated size, font, and position. Other mandated information, such as health warnings, would remain, as illustrated below.*

"Regular" Packaging

"Plain" Packaging
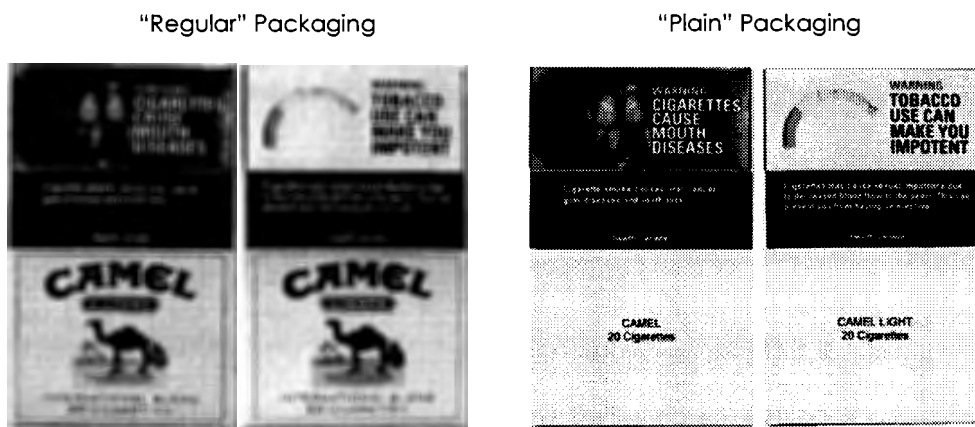
One alternative to the example above would be to minimize the proportion of "plain" or "generic" background by enhancing the size of health warnings—see example at right.[52] For example, research conducted in Canada indicates that pictorial health warnings that cover 90 to 100% of the principal display areas may have similar effects to "plain" packaging.[52,53]

Plain packaging and brand appeal

Plain packaging has three potential effects. First, removing the colours and brand imagery from packages has the potential to reduce brand appeal. Research to date suggests that plain packages are less attractive and engaging, particularly to young people.[37] For example, a survey of Canadian youth found that strong majorities "liked" regular packages better than plain packages, and indicated that plain packages are more "boring" and "uglier" than regular packages.[184] Approximately one third of respondents also reported that young

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* Note that plain packaging would not address misleading brand descriptors—the term is typically used to refer strictly to the removal of colour and brand imagery. Therefore, prohibitions on misleading words and numbers on packages likely requires a separate regulatory measure.

people their age would be less likely to start smoking if all cigarettes were sold in plain packages. A similar study of Canadian and U.S. youth found that plain packages reduced the positive imagery associated with packages and were associated with greater negative imagery.[185] Recent research conducted with adult smokers in Australia also found that, "cardboard brown packs with the number of enclosed cigarettes displayed on the front of the pack and featuring only the brand name in small standard font at the bottom of the pack face were rated as significantly less attractive and popular than original branded packs. Smokers of these plain packs were rated as significantly less trendy/stylish, less sociable/outgoing and less mature than smokers of the original pack."[186] Similar results have emerged from a recent study conducted in the UK: adult smokers and children rated generic versions of packages as significantly less attractive and youth were less likely to select a general brand if they were to try smoking. [171] Marketing research conducted with adults also suggests that plain packaging reduces some of the appeal of smoking, as the follow quote indicates:

Trachtenberg (Forbes Magazine, 1987)

"...when we offered them Marlboros at half price--in generic brown boxes --only 21% were interested, even though we assured them that each package was fresh, had been sealed at the factory and was identical (except for the different packaging) to what they normally bought at their local, tobacconist or cigarette machine.' How to account for the difference? Simple. Smokers put their cigarettes in and out of their pockets 20 to 25 times a day. The package makes a statement. The consumer is expressing how he wants to be seen by others."[187]

Plain packaging and perceptions of risk

Plain packaging also has the potential to reduce false beliefs about the harmfulness of different cigarette brands. Considerable proportions of smokers in countries such as Canada, Australia, the US, and the UK continue to believe that some types of conventional cigarette brands are less harmful than others.[156] A recent study conducted with adult smokers and youth in the United Kingdom found that, when asked to compare varieties from 8 different cigarette brands, approximately 75% of

adult smokers and children falsely reported that there were differences in risk between at least one of the varieties.[171]

Plain packaging and the salience of health warnings
Plain packaging can also increase the effectiveness of health warnings.[188] In one study, New Zealand youth were significantly more likely to recall health warnings when they were presented on plain packs compared to health warnings presented on "normal" branded packages.[189] A series of surveys and experiments conducted in Canada also demonstrate that health warnings on plain packages are more noticeable, easier to recall, and more believable.[185,27] In 1995, an expert panel from Canada summarized their conclusion on plain packaging based on a comprehensive review:

> **Expert Panel Report on Plain and Generic Packaging (Canada, 1995)**
> *"Plain and generic packaging of tobacco products (all other things being equal), through its impact on image formation and retention, recall and recognition, knowledge, and consumer attitudes and perceived utilities, would likely depress the incidence of smoking uptake by non-smoking teens, and increase the incidence of smoking cessation by teens and adult smokers."*[27]

To date, plain packaging regulations have been considered in several jurisdictions, but have yet to be adopted.[183,190] Industry opposition to plain packaging measures can be expected to be robust. A "plain packs group" was created in 1993 with representative from leading tobacco companies.[191] Documents from this group clearly state that the group did not "want to see plain packaging introduced anywhere regardless of the size and importance of the market."[192]

In recognition of the evidence on "plain packaging" the Elaborated Guidelines of FCTC Article 11 state that:

FCTC Article 11 Elaborated Guidelines

"Parties should consider adopting measures to restrict or prohibit the use of logos, colours, brandimages or promotional information on packaging other than brand names and product names displayed in a standard colour and font style (plain packaging). This may increase the noticeability and effectiveness of health warnings and messages, prevent the package from detracting attention from these and address industry package design techniques that may suggest that some products are less harmful than others..."[104]

Evaluating the removal of information on packages

Unlike other tobacco labelling policies, restrictions on misleading information result in the removal, rather than the provision of information. This presents a challenge when evaluating the impact of these policies, particularly when the information being removed is used as a brand descriptor. In the case of *light* and *mild* bans, the terminology that was previously used to identify a class of products no longer exists. Smokers may retain the same misleading perceptions of these products after the terms have been prohibited, but research measures can no longer refer to "light" or "mild" cigarettes in the same way as in the past. Therefore, survey measures must be designed so that the wording and meaning of questions remains constant before and after the removal of these terms. This creative challenge is only now being confronted by researchers with the recent advent of *light* and *mild* prohibitions.

Another implication of the "removal" of brand information is that the beliefs associated with *light* and *mild* cigarettes are likely to persist for some time after the descriptors disappear from packages. This situation is similar to advertising, promotion, and sponsorship bans: one should not expect beliefs to change immediately upon the implementation of the policy, but more gradually over time. Indeed, anecdotal evidence suggests that many retailers and consumers continue to use the terms *light* and *mild* well after their removal from packages. This issue is distinct from, but complicated by the effect of new descriptors, which are designed to act as substitutes for the banned terms. These considerations are important in terms of how the "effectiveness" of prohibitions on packaging information are evaluated.

DESIGNING HEALTH WARNINGS

Background

The focus of the current chapter is on planning and designing effective health warning messages. To date, countries have taken much different approaches to the design and selection of health warning messages: some countries, such as Canada and Australia, have invested considerable time and resources in the development of health warnings, whereas other countries with fewer resources at their disposal have adopted a more streamlined process. The goal of this chapter is to simplify this process into a series of steps that can be adapted to local needs and the availability of resources.

Step 1: Layout and Design

The first step in developing health warnings is to determine the general layout and design. Key elements include the size, position, borders, and general appearance of the warnings. The figures below illustrate three different approaches to the design and layout of pictorial warnings.

Canada

"Front" (50% size)   **"Back" (50% size)**

"Marker" word

"Tagline"
Black letters

English Text

Attribution to
health authority

Same warning with
French text

Belgium/European Union

"Front" (48% size)   **"Back" (63% size)**

Text (3 languages)

Bolded border

Picture with border

Text (3 languages)

Australia

"Back" (90% size)   **"Front" (30% size)**

"Tagline" White letters/ Red Background

Attribution to "Health Authority"

Picture with title

Explanation

Cessation information

"Tagline" White letters/ Black Background

Attribution to "Health Authority"

Picture with title

General considerations

Size of warnings

The FCTC requires that warnings must be a minimum of 30% and should cover at least 50% of the principle display areas of the pack. In practice, 50% should be

considered the minimum, while even larger warnings will have even greater effectiveness. In many cases, the size of the warnings is the same on both the "front" and "back" of packages; however, some jurisdictions have used different sizes for each side. In Australia, for example, pictorial warnings cover 30% of the "front" of the package, and 90% of the "back"; in Brazil, warnings cover 100% of either side. Regardless of whether warnings are different sizes, they should cover at least <u>50% of each principle display surface</u>. This ensures that the warnings are perceptible regardless of which package face is visible. This is especially important at the point-of-sale in retail outlets, where cigarette packages are often seen by children and youth.

Position of warnings
Health warnings should be positioned at the "top" of principle display surfaces in order to maximize their effectiveness at the point-of-sale.

Position of pictures and text
Warnings that occupy a smaller portion of the packages and are rectangular in size, often position the picture and the text horizontally, with the picture to the left and the text to the right (see the example on the "front" of Australian packages, above). Larger warnings that cover half the package or more, typically place the picture above the text description (see the example on the "back" of Australian packages). The amount of space dedicated to the picture versus the text varies across jurisdictions. As discussed, below, some jurisdictions include very little descriptive text. Regardless, the <u>picture should appear on both the front and back of packages</u> and occupy <u>at least half of the space</u> devoted to warnings.

Marker Word

A common feature of warning labels and signs is to use a "marker" word such as
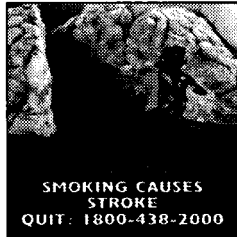
"CAUTION", "DANGER", OR "WARNING." Packages in several jurisdictions use "WARNING" as a marker word—see the example from Singapore, at left. In most cases, the font size of the marker word is larger and written in a different colour than other text in the warning.

Tagline

The headline or "tagline" serves as a summary of the main message and is used in conjunction with the picture to attract attention. Jurisdictions will need
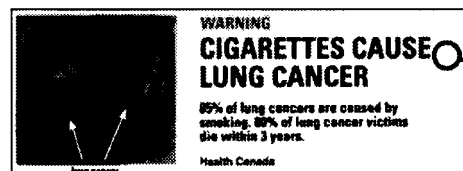
to choose the position of the tagline. In many cases, the tagline is displayed either at the top of the warning, above the image, or beside the image, immediately preceding the "explanation" text (see example from Canada, above). The tagline should have sufficiently large, bolded font to be clearly legible and to stand out from the warning. Note that the colour of the font and background should contrast in order to maximize legibility. Black lettering on white background and white lettering on black background are examples of effective contrast.

Explanatory text

Many warnings include several sentences of text to help explain the health risk depicted in the picture and the tagline. Although the amount of explanatory text differs considerably across jurisdictions, it should be considered an important element of the warnings. The font size of the explanatory text will typically be smaller than the tagline, but must still be large enough to be easily read.

Attribution of message

Warnings in many countries include text attributing the health warning to the government or some other source. Often, the name of the health ministry is included in small letters at the end of the warning. In other cases, the attribution is included as part of the preamble to the warning, such as: "The Department of Health and Welfare advises…". In countries where the government health ministry is well regarded and has high credibility, attribution to a government source may increase the believability of the information; however, if the government is generally disliked or mistrusted, attribution to government sources may result in rejection of the health warning. Attributions also require valuable space that could be devoted to other information. It should also be noted that the tobacco industry has previously lobbied for government attribution, perhaps to distance itself from the health messages. Overall, however, there is no clear consensus as to whether attributions increase or decrease the credibility of warnings. If attributions are included as part of the warning, the attribution should be made to a health authority rather than the government in general. The attribution should also be relatively small to minimize the space it occupies and should appear at the bottom or end of the text message, rather than at the beginning.

Interior of Package

The external display surfaces of the package represent the most important "real estate" for health warnings or any other information. However, there are also possibilities for using the "inside" of packages. Canada currently requires one of 16 messages to appear on the inside of packages—see right. Although this information is significantly less noticeable than the health warnings on the exterior of the package, interior messages nevertheless represent an added opportunity to communicate with the smoker

which some jurisdictions may wish to pursue. Similar opportunities exist with respect to "onserts", messages attached to the outside of packages.

◉ *"Should we conduct research to test the layout of warnings?"*

The general recommendations for size, position, and layout are based upon various research studies conducted across several countries. (See the Evidence Review in Chapter 1 for a comprehensive review.) The basic principles of design and layout appear to be universal: pictorial warnings, for example, appear to be more effective than text-only warnings in every region in which they've been evaluated. Although jurisdictions with considerable resources may wish to test variations on the basic principles of layout and design, there is little need for most jurisdictions to conduct new research to demonstrate these basic principles with respect to size, position, and the use of pictures. The exception may be where politicians or decision-makers require local evidence, in order to be persuaded of the additional benefits of pictorial vs. text-only warnings, or larger warnings, for example. Recommendations for testing design and layout features are included in Chapter 5.

Step 2. Select Number of Warnings and Rotation Period

The FCTC requires that health warnings are "rotated" on packages. Jurisdictions will need to determine the number of warnings per rotation (or "set" of warnings) and the rotation period (or time between sets). For example, Australia recently implemented a set of 7 warnings that will be revised with a second set of 7 warnings after 12 months. Given the time and political resources required to develop and implement new health warnings, developing more than one set of warnings and stipulating a rotation period is an efficient use of resources and ensures regular updates to the warnings.

There is no consensus on either the ideal number of health warnings within each set or the ideal rotation period. In general, each set of warnings should include anywhere from 8 to 12 individual warnings that will appear concurrently. Each set of warnings should be rotated approximately every 1 to 2 years, and no more than every 4 years. Decisions about the number of health warnings in each set and rotation periods must be made early in the process in order to determine how many warnings will need to be developed.

⊚ **RESOURCE: Layout and Design Worksheet**

A worksheet is included at the end of this chapter to help simplify the steps and decisions that must be taken regarding the layout and design of warnings (see Worksheet #1). Using this worksheet will help to ensure that you have considered all of the major issues before going on to consider the content of the health warning messages.

Step 3: Review Existing Warnings

Before developing new health warnings, existing health warnings in other jurisdictions should be examined to help generate ideas and identify possible themes. To date, well over a dozen countries have recently implemented large pictorial warnings that satisfy the general recommendations for layout and design. Some of these jurisdictions have also developed several sets of health warnings.

⊚ **RESOURCE: Picture Warnings Online**

An extensive list of picture-based health warnings that have been implemented throughout the world, as well as additional images used in test-marketing, can be reviewed at: www.tobaccolabels.org

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Step 4: Content—Identifying Themes & Subjects

Health warnings should be thought of in terms of a communication strategy. Before developing specific warnings, the basic objectives and broad themes of new health warnings should be identified. Broad themes might include addiction, health effects of tobacco, cessation, and various "other" costs of tobacco use, including financial and social costs. While it is possible to target many or even all of these broad themes within a set of health warnings, some jurisdictions have given priority to certain themes in terms of the number of warnings devoted to each.

Possible themes and subjects for health warnings		
Theme	**Sub-theme**	**Subject**
Addiction	Addictive substances Testimonial Facts & statistics	
Cessation	Benefits of quitting	○ Health benefits ○ "Other" benefits
	Supportive "efficacy" messages Quitting tips	
	Cessation services & sources of support	○ Telephone helpline ○ Internet sites
Health effects	Effects on self	○ General morbidity & mortality ○ Specific types of disease ○ Quality of life
	Effects on others	○ Second-hand smoke and types of disease
Toxic Constituents	List of chemicals Effects of chemicals	○ Specific chemicals
"Other costs"	Financial costs Social costs Aesthetic costs Manipulation	

Each of these broad themes includes several sub-themes and specific subjects. The table above presents common sub-themes and subjects that have been targeted in health warnings to date. For example, the general theme of "health effects" includes sub-themes such as "effects on self" and "effects on others", as well as dozens of specific health effects that serve as the subject of each warning.

Health effects

Depictions of health effects include messages on the general risks of tobacco use (e.g., "Smoking Kills" or pictures of a cadaver or skull), as well as messages on specific health effects or diseases. Specific health effects often include the leading causes of smoking-related death and disability, including cancer, lung disease, heart disease, and stroke. "Novel" diseases that may be responsible for fewer deaths may also be featured in order to communicate the wide range of health effects associated with tobacco use. For example, Australia recently included warnings for blindness and peripheral vascular disease (gangrene) alongside more "conventional" health effects.
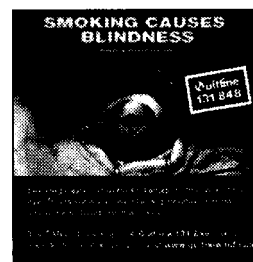
In either case, health warnings should not simply promote a basic awareness that smoking causes disease. Messages should target the perceived likelihood and the perceived severity of health effects—two critical components of risk communication. For example, although many smokers know that smoking causes lung cancer, there are many effective and novel ways to communicate the suffering, loss, and personal experience of lung cancer.

Also note that perceived severity is a fairly broad concept. From a public health perspective, severity is most often calculated in terms of the number of lives

attributable to a particular disease. However, from the individual's perspective, perceived severity may be more closely related to the consequences in terms of quality of life or the consequences to ones physical appearance. For example, the health warning for mouth diseases that originally appeared on Canadian packages in 2000 (see below) has been copied in jurisdictions throughout the world and is among the most recognizable and effective package warning developed to date. This warning is not more effective because mouth cancer is any more common or severe than lung cancer or stroke; rather, the mouth cancer warning is effective because it depicts a "gross", aesthetically displeasing health effect. To many smokers, "gross" effects to one's physical appearance may be perceived as more severe than more lethal health effects. Overall, health warnings that increase smokers' perceived likelihood and severity of risks are likely to be most effective. Different techniques and presentation styles for making health effects more vivid and personally relevant are discussed in the next chapter.

Messages targeting health effects should also link common experiences and early symptoms of smoking with serious disease. For example, messages should link serious lung disease with common symptoms such as wheezing, shortness of breath, coughing, and phlegm. (E.g., "Wheezing is the first sign of lung damage that can lead to emphysema and the use of an oxygen tank later in life.") Phlegm may be particularly effective given the negative association of this word.

Cessation

Effective risk communication requires two other critical elements: the *perceived benefit* of changing behaviour or, in this case, quitting smoking, and concrete information on *how* to change. As a result, cessation should be regarded as a critical theme of health warning messages. Cessation information can be broken down into four sub-themes: 1) Information on the benefits of quitting (including both the direct health effects, as well as related benefits, such as improvements in quality of life); 2) General "efficacy" information—supportive messages that are intended
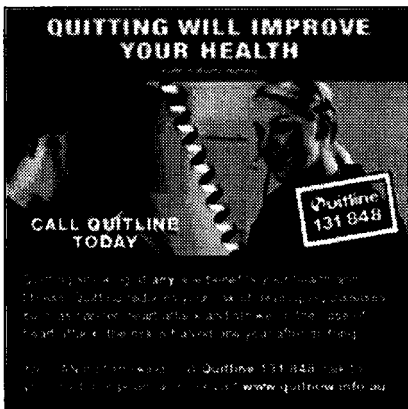
to build confidence and motivate a quit attempt; 3) Tips for quitting smoking; and 4) Information on cessation services, such as telephone helpline numbers and internet services. Telephone helpline numbers have proven an especially effective type of information to include, as discussed in Chapter 2.

Toxic constituents & Product-related messages

There is general consensus that health warnings should help to inform smokers about the toxic chemicals in tobacco products. Many jurisdictions require a separate set of health messages on the side of packages to communicate this information—these messages are the subject of Chapter 4. However, some jurisdictions have also chosen to feature constituent information in one of the "main" health warnings on the face of packages—see example at right.
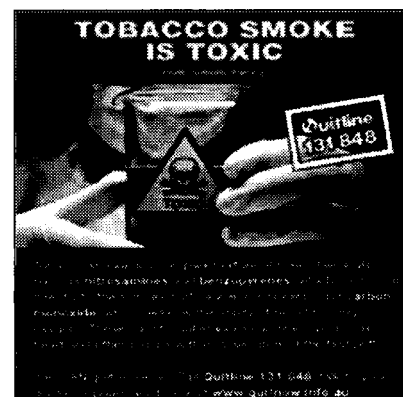
Health warnings could also be used to communicate other important product information. For example, warnings could target widespread misconceptions, such as the belief that "low-tar" products are less hazardous.

Addiction

Several countries have implemented warnings that communicate the addictive properties of cigarettes. Addictive messages should target younger audiences, who may not have personal experience with nicotine dependence. As a result, any smokers portrayed in these warnings should be younger to maximize personal identification with these messages. Focus group testing has occasionally found that messages on addiction are not rated as highly as warnings depicting health effects, largely due to less effective pictures and images. Pictorial warnings on addiction often use "abstract" images that lack the same emotional engagement and vividness of graphic depictions of disease. In addition, simple statements that "smoking is addictive" may not be particularly helpful to the vast majority of smokers who already have personal experience of nicotine dependence. Addiction messages should focus on the consequences of smoking in a way that communicate the essence of addiction, while linking it with a vivid health effect— see example below:
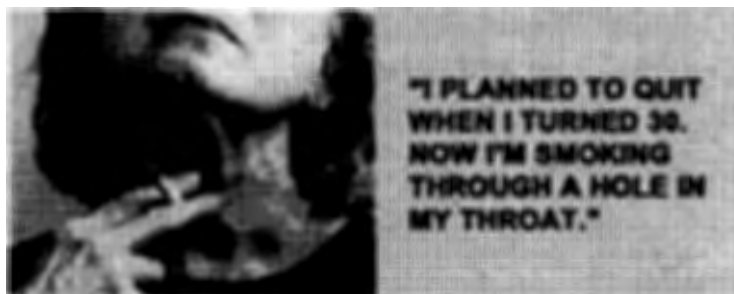
"Other" effects

Some jurisdictions have chosen to target other, non health-related effects in warnings. For example, messages reinforcing the financial costs of smoking help to remind smokers of a very powerful incentive for quitting. Other warnings have highlighted the aesthetic costs of smoking, particularly in terms of physical appearance. These include physical effects that may not be particularly significant in terms of health, but may nevertheless be valued by smokers: stained teeth, wrinkled skin and other aspects of ageing. Some health warnings have also sought to highlight the social consequences of smoking and social norms. For example, the warning developed in the European Union at right,

Smoking may

and

highlights the potential embarrassment associated with impotence from smoking and may help to undermine the social desirability of smoking.
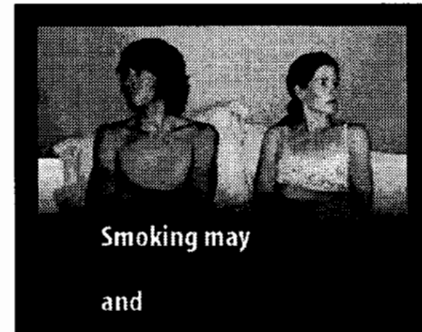
Themes of "counter-marketing" and exploitation could also be targeted through health warnings. Although these themes have been successfully used in mass media campaigns to target younger audiences, they have yet to be featured in health warnings.

Targeting multiple themes

Many health warnings incorporate several message themes within the same warning. In fact, research suggests that health warnings are most effective when "threatening" information on health effects is paired with strong efficacy messages to support behaviour change. In other words, each warning should include themes of cessation information along with messages on health effects. Health warnings from Australia, shown below, provide a good illustration of this principle.

Health effects theme

Cessation efficacy and services
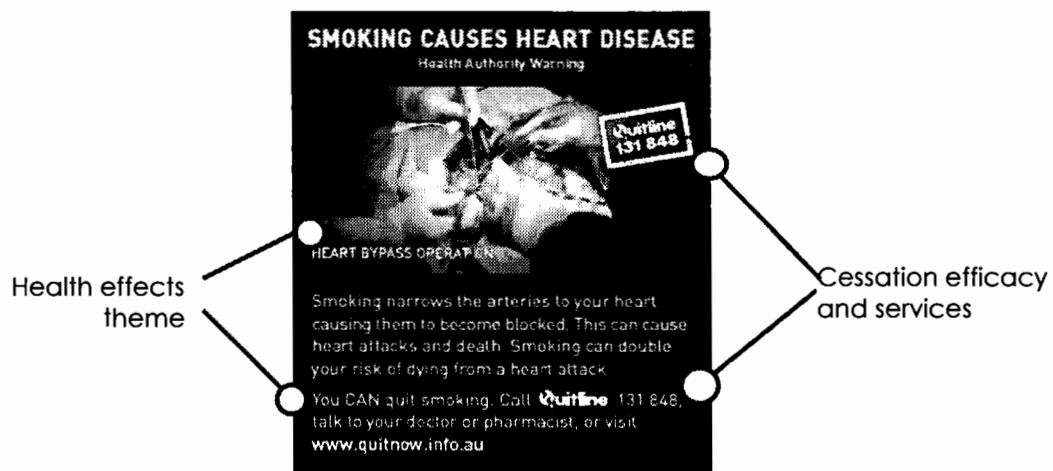
Target groups

Many health warnings are tailored to particular sub-groups of smokers. Some warnings are gender-specific or targeted towards a particular age group, such as warnings on the risks of smoking while pregnant. Many warnings related to second-hand smoke also focus specifically on smokers with children in the household. The decision to target sub-groups should be part of the general discussion regarding priority themes and subjects.

Summary

The final decision regarding which themes and subjects to select will vary for each country. The decision should be guided in part by the following:

- What are the existing levels of health knowledge in the population?
- What messages are included in previous and existing sets of health warnings?
- Are there specific diseases or areas of health knowledge that are considered a priority?

At the end of Step 4, you should have a list of priority themes. It is essential that the process for making these decisions include individuals familiar with the local population and with the domestic tobacco control environment.

⊚ "What about health warnings for "other" types of tobacco products?"

The FCTC Article 11 includes all tobacco products; however, health warnings for cigarettes are more advanced than for other tobacco products. In countries, such as Canada, packages for "other" tobacco products, such as cigars and smokeless tobacco, also carry warnings, although these warnings often have a different content than the cigarette warnings. This is important given that some of the specific health effects are different between combustible and non-combustible forms of tobacco, as are some of the toxic constituents.

The size and position of the warnings for non-manufactured cigarette products may also need to be adapted. The images below provide several illustrations of how the layout and design of Canadian health warnings have been adapted to fit different forms of packaging.

Overall, when developing health warnings, be sure to ask:

- Are there any local forms of tobacco use that should be taken into account when selecting themes?
- What are the common packaging forms and sizes?
- To what extent, does the content of the health warnings need to be adapted for alternative products?

In some cases, separate health warnings may be required for different classes of product, such as smokeless forms of tobacco.

Step 5: Images & Presentation Style

The quality and style of the picture is the most important determinant in the effectiveness of a health warning. Even though a warning may include informative text for an important health effect, the impact of the warning can be limited by the wrong image. Images are particularly important in the long-term effectiveness of warnings.

Once the theme and subject of a warning have been identified, the goal is to develop images to make the information as vivid and personally relevant as possible. "Neutral" images that fail to elicit an emotional reaction should be avoided at all costs. The effectiveness of picture warnings is often highly specific to the particular image—even small differences in the content and configuration of the image can have a large impact on its effectiveness. The first step in constructing an image is to decide on the general "presentation style." The following sections describe several common presentation styles for health warnings.

Graphic depictions of disease

Research in the field of health communication indicates that messages with emotionally arousing content are more likely to be noticed and processed by smokers. Previous research indicates that one of the most effective ways of arousing emotion is to use "graphic" pictures of health effects. Some jurisdictions, such as Singapore, have adopted this approach for the entire set of warnings (see right). Focus group

64
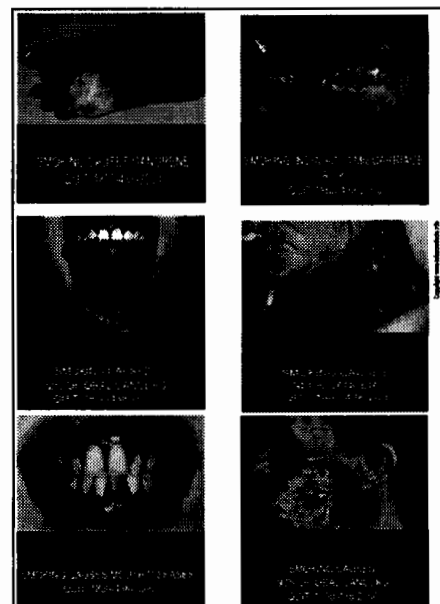
testing has indicated that graphic pictures that also show the victim's face add personal relevance to the graphic depictions. As noted previously, graphic depictions are also most effective when paired with supportive cessation information.

◉ *Are there other ways to elicit emotion besides graphic pictures?*

Although graphic depictions of disease may be the most reliable way of eliciting an emotional response, there are other ways of doing so. These often involve pictures depicting the human consequences of disease or messages that connect directly with the smoker. Two examples are provided below. In both cases, the warnings appeal directly to the viewer and add a poignant "human" element to the costs of tobacco use. In the two examples below, the warnings also highlight the consequences for important "others", such as the family and children of tobacco users.


Testimonials

Testimonials are an excellent way to increase the personal relevance of health warnings. Testimonials are often used to communicate a health effect, but they do so within the context of a narrative or story. Providing personal information about "real" victims, such as their name, adds important context and attaches a "human" face to health effects. Testimonials are also highly credible—it is very difficult for

sceptics to reject health risks when they are presented with a real example. Indeed, one of the most common questions asked by smokers during focus group testing is whether the people depicted in the health warnings are real. (For this reason, even warnings that do not adopt a testimonial style should use real people as often as possible). Testimonials may also be a particularly effective way of communicating addiction and cessation themes, although these approaches have yet to be utilized to date.

⊚ **CASE STUDY: Testimonial warnings**

Health warnings in Chile feature Don Miguel, a victim of larynx cancer from smoking. The Chilean warnings were the first to feature a real-life testimonial on package health warnings.

DON MIGUEL, CHILENO, FUMO 20 AÑOS. PERDIO SU LARINGE POR CANCER
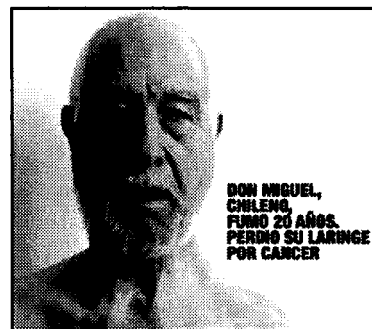
Aesthetics & Personal experience

Some warnings have specifically targeted the effects of smoking on physical appearance, such as yellowed fingers, stained teeth, wrinkled skin, and other

effects on ageing. Negative effects on physical appearance may be particularly effective among youth and younger adults, given that the long-term health effects are more remote and may hold less value for younger populations.
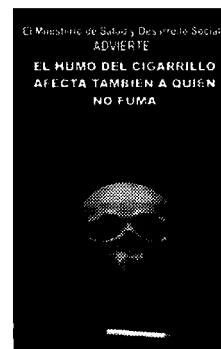
Cultural Symbols & Icons

The use of pictorial symbols is a common and effective feature of health warnings for a wide variety of consumer products. For example, the globally harmonized

system (GHS) of classification and labelling of hazardous chemicals (GHS) uses the skull and crossbones as the universal symbol for toxic substances.

Some jurisdictions have used symbols or icons to communicate the risks of smoking. For example, several countries have used a skull to communicate the general risks of smoking (see Venezuelan warning at right). Using widely recognized symbols of death and danger may be an effective approach to risk communication, particularly in regions with low levels of literacy and little existing knowledge of specific diseases or health effects. However, cultural symbols must also be used cautiously, so as not to cause offence or lead to rejection. In Thailand, for example, a warning using a culturally sensitive symbol of a burial proceeding met with some public resistance and was subsequently removed from the warning.

Humour

Humour represents another option for presentation style. Warnings for impotence that use the image of a limp cigarette are the most common example to date (see Brazilian example at left). Although humour may be an effective presentation style in some cases, it should be used with great care so as not to trivialize the importance of health risks.

General principles

In addition to specific presentation styles, there are several general principles for developing the images in health warnings.

- Pictures should be as striking and colourful as possible, and have high resolution.
- Persons depicted in warnings should be somewhat younger, rather than older. Whereas older adults are able to relate to pictures of younger adults, the reverse

is not necessarily true. Using younger adults in pictures also makes the health effects somewhat more immediate for younger smokers.

- Although there is no evidence that health warnings actually increase smoking, it is nevertheless important to avoid pictures that may serve as smoking "cues" for some individuals. For example, some focus groups and one experimental study have found that pictures of cigarettes, smoke from a lit cigarette, and pictures of ashtrays may serve as a cue for some participants and are rated as more pleasant by smokers.[2]

Step 6: General Recommendations for Text

The amount of text included with pictorial warnings varies considerably across jurisdictions. In some countries, only a title or tagline accompanies the picture, while other countries include several sentences or paragraphs of explanatory text. Regardless of the amount of text, several basic principles apply:

- All text should be consistent with the themes and subject depicted in the picture.
- In all cases, text messages should be as clear and direct as possible.
- Text should be at an appropriate literacy level.
- The colour of the font and background should contrast in order to maximize legibility. Black lettering on white background or white lettering on black background are examples of good contrast.

Tagline

The tagline should be relatively concise (e.g., no more than a sentence) and provide a clear summary of the warning presented in direct, unequivocal language.

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[2] See: B E M Nascimento, et al., Avoidance of smoking: the impact of warning in Brazil. *Tob. Control* 2008;17;405-409.

Explanatory text

- In all cases, the text should be simple and straightforward: less text that is easier to read will be more effective than long sentences with confusing detail.
- Technical language should be avoided and all text should be understandable by smokers with low literacy levels.
- Text should avoid equivocal language that may create uncertainty or doubt about the risks depicted in messages. Text should not use words such as "can", "may", or "might", when describing health risks. For example, warnings should read "Cigarettes cause lung cancer", rather than "Cigarettes can cause lung cancer."
- Statistics and numbers should be used only in rare cases. Most smokers do not understand even simple statistics and, on their own, numbers may prove misleading. If numbers or statistics are used, they should be presented as simply as possible and should be focus group tested during the development of warnings.

Multiple languages

Health warnings in countries with multiple languages require special consideration. In Canada, which has two official languages, the same warning appears in French on one side of the package and in English on the other side. Other jurisdictions have included more than one language in the same warning. For example, the Belgium warnings, shown at right, display the text in Dutch, French, and German. Because this requires additional space, the size of the Belgian warnings is larger than the minimum European Union standard. Another option is to create separate warnings in each language and then stipulate that the warnings from each language be randomly printed on different packages. In all cases, the use of pictures accompanying the text will be extremely important, given that pictures are universal across languages.
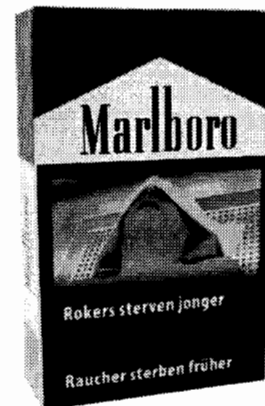
Step 7: Develop Warnings

By Step 7, the general layout of the warnings should be established, as well as the specific themes and subject matters to be targeted. At this point, the individual warnings can be developed for testing. Several "concepts" should be developed for each theme and subject in order to determine the best creative execution of each. In other words, several different warnings should be designed that take slightly different approaches to communicating the same message. See the examples on the following page, which were used by the United Kingdom Department of Health to identify which of the three concepts should be selected. Three concepts were tested for each main message or "theme." See Chapter 4 for recommendations on testing concepts.

"Smoking can cause a slow and painful death."

Using existing warnings

The easiest and most cost effective option when developing warnings is to use existing health warnings from other jurisdictions. Seeking permission to use existing warnings is an excellent option for jurisdictions without resources to develop original images and warnings. In some cases, the copyright permission to use pictures from another country may be available; however, even in cases where permission to use an existing warning from another country is not granted, these warnings can nevertheless serve as templates to be modelled.

Developing "new" warnings

Where resources permit, countries should attempt to develop warnings tailored for their own country. This may be important for several reasons. For example, warnings that include pictures of people should broadly represent the ethnic/racial profile of each country. It would be inappropriate to include images of caucasians from Canadian warnings in health warnings for China, for example. Certain images, symbols, or other references may also be culturally specific. In some cases, existing warnings may only require small changes, although many jurisdictions may decide to create completely original warnings to suit their own needs, where resources allow.

A number of countries have hired advertising agencies or communication experts to develop new messages. Countries should always use professional agencies when resources allow; however, some jurisdictions have adopted less costly methods, including taking pictures at local hospitals. Regardless, at the end of Step 7, you should have a set of specific health warnings dedicated to each priority theme.

Designing Health Warnings—Worksheet #1

WORKSHEET FOR LAYOUT & DESIGN OF HEALTH WARNINGS

1. General
Number of "sets" or "waves" of warnings?
Rotation time period per "set" or "wave"?
Number of warnings per "set" or "wave"?
Total number of warnings to be developed?

2. Layout of warnings
General
- Size of warnings (% of front and back)?
- Position of warnings?
- Borders?
- Picture or text only?
- Background colour?
- Position of text and picture?
- Text colour?
- Number of languages to be used?

Marker word (Yes/No)
- Position
- Font size
- Font colour

Tagline
- Position
- Font size
- Font colour

Explanatory text
- Position
- Font size
- Font colour

Attribution (Yes/No)
- Attribution source
- Position
- Font size
- Font colour

3. Priority themes & subjects

- What are the priority themes and subject matters?

4. "Other" tobacco products
- What tobacco products other than manufactured cigarettes are commonly sold in the market?
- How should the content of warnings be adapted?
- How should guidelines on the size and position of warnings be adapted to suit different forms of packaging in which these products are sold?

Designing Health Warnings—Worksheet #2

WORKSHEET TO BE COMPLETED FOR EACH HEALTH WARNING CONCEPT

1. **Theme(s)**
   What are the general themes and sub-themes of this warning?

2. **Subject**
   What is the main subject of this warning?

3. **Target audience**
   Is there a particular target audience for this warning?

4. **Presentation style**
   What is the general presentation style of the warning?

5. **Picture**
   Is the picture clear and easy to understand?
   Does it have immediate impact?
   Does it arouse emotion or interest?
   Does it lead to interest or curiosity in the explanatory text?

6. **Tagline**
   Does the tagline provide a concise summary of the warning?
   Does it stand out from the rest of the text?
   Is it consistent with the picture?
   Is it targeted at the appropriate literacy level?
   Is it simple, direct, and easy to understand?
   Is the literacy level sufficiently low?

7. **"Explanatory" text**
   Is the text easy to understand?
   Is it believable?
   Are there any confusing elements?
   Is the literacy level sufficiently low?

8. **Cessation message**
   Is cessation information included in each warning?

DESIGNING EMMISSION & CONSTITUENT WARNINGS

BACKGROUND

The goal of this section is to provide recommendations and steps for designing emission and constituent messages on packages. Although this aspect of labelling is more straightforward than designing health warnings, it presents unique challenges. Cigarette smoke contains approximately 4,000 chemicals, including over 60 carcinogens and toxins, such as formaldehyde, benzene, and hydrogen cyanide. Although there is general agreement that cigarette packages should provide some information on these chemicals, regulators continue to struggle with how best to communicate this information in a feasible and meaningful way to consumers.

Article 11 of the FCTC currently requires that packages contain "information on relevant constituents and emissions of tobacco products as defined by national authorities"; however, there remains considerable confusion regarding what constitutes "relevant" information. Some regulators have required manufacturers to print the levels of three emissions (tar, nicotine, and carbon monoxide) on the side of packages. This remains the most common practice throughout the world. However, there is strong evidence that printing emission numbers on packages should be immediately abandoned given that it reinforces the tobacco industry's deceptive marketing campaign and the false belief that low tar cigarettes are less hazardous. For example, the Elaborated Guidelines for FCTC Article 11 state that: "Parties should prohibit the display of figures [i.e. numbers] for emission yields, such as tar, nicotine, and carbon monoxide, on packaging and labelling, including when used as part of a brand name or trademark."[3] A more complete explanation of these issues is provided in Chapter 1.

At present, the most effective practice for meeting the Article 11 guidelines is to provide non-numerical descriptive information on emissions and constituents. The

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[3] Conference of the parties to the WHO Framework Convention on Tobacco Control. Final Report Committee A. World Health Organization, 2008. Available at: http://www.tobaccolabels.ca/fctcandh/fctcarticl

current section provides recommendations on how to follow and improve upon existing practices in descriptive emission and constituent messages.

◉ *"What is the difference between a constituent and an emission?"*
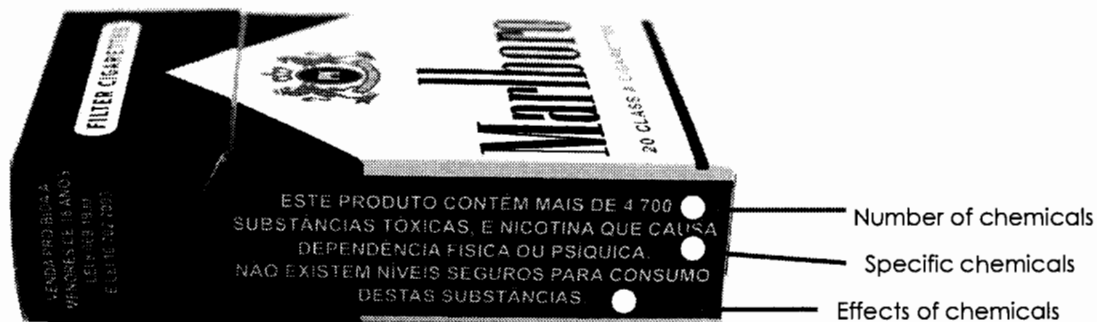
Constituents generally refer to the chemicals and substances in un-burnt tobacco. This includes "additives", as well as chemicals naturally present in tobacco. *Emissions* refer to the chemicals released by products when they are used by consumers. Although all tobacco products have emissions, the term is usually used to refer to the chemicals found in the smoke of combustible products. Smoke emissions are tested using a machine that "smokes" cigarettes according to a fixed puffing regime then collects and analyzes the smoke. Neither the levels of constituents or emissions in cigarettes are a good predictor of what humans ingest, mainly because each smoker adapts their behaviour to the type of cigarette. A more complete explanation of these issues is provided in Chapter 1.

Step1: Layout and Design

The figure below illustrates two recent approaches to the design and layout of the emission and constituent messages.
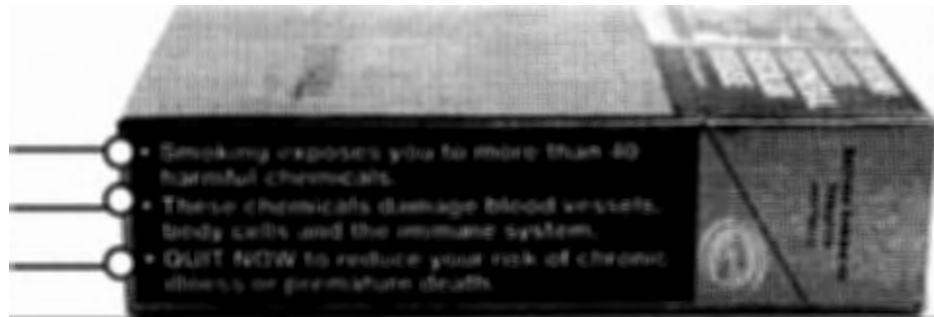
Brazil

Labels pointing to the cigarette pack:
- Number of chemicals
- Specific chemicals
- Effects of chemicals

Text on pack:
ESTE PRODUTO CONTÉM MAIS DE 4 700 SUBSTANCIAS TÓXICAS, E NICOTINA QUE CAUSA DEPENDÊNCIA FISICA OU PSIQUICA. NAO EXISTEM NIVEIS SEGUROS PARA CONSUMO DESTAS SUBSTANCIAS

Australia

Size & Position

Size & Position

Emission and constituent messages are typically located on one side of the package. Many jurisdictions have used the entire side, up to the point where the package separates for "flip-top" packages, to avoid cutting off the text information (see example above). However, in some cases, manufacturers use a different background colour and print company information on the "unused" section. In the future, this portion of the pack should be in the same colour as the rest of the TEM (e.g., black) and should either remain blank or should feature the toxic skull symbol, which would appear on either side of the text message. The picture below illustrates this concept using a yellow line to depict the part of the pack that opens.
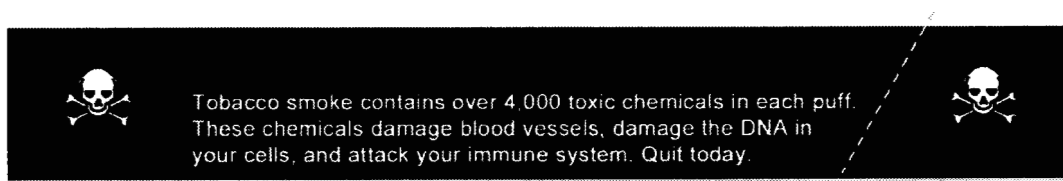
Contrasting colours

As with health warnings, it is important to ensure high contrast between the wording and the background. White letters on black background or black letters on white background are the most effective combinations. The font size should be sufficiently large to be legible.

Use of symbols and pictures

The most consistent finding from both quantitative and qualitative research conducted among tens of thousands of smokers throughout the world is that pictures enhance the effectiveness of health warnings. The same principles that have been adopted in designing the primary Health Warning Messages should be applied to the toxic and constituent message on the side of packages: use pictures to attract attention and improve risk comprehension.

To date, no jurisdictions have included symbols or pictures in the side messages for emissions and constituents. Previous research with international hazard symbols indicates a picture with signal word, a hazard/marker word, and a precautionary statement is most effective. Pictures can be used in two ways to increase the vividness of these messages. First, a symbol that is widely recognized as a warning for poisonous or dangerous goods could be added to the text. The skull and bones used by the globally harmonized system (GHS) of classification and labelling of hazardous chemicals is one example (see right). There is extensive evidence that using the GHS toxic symbol increases the salience and comprehension of toxic chemical warning messages.[4]

For example:

- Symbols allow consumers to avoid hazards in their environment because they attract attention.[5,6]
- Symbols act as reminders to perform necessary safety behavior by cueing existing knowledge within memory.[7]

[4]Dewar RE. 1999. Design and evaluation of public information symbols. In: Zwaga HJG, Boersma T, Hoonhout HCM, editors. Visual information for everyday use: Design and research perspectives. London: Taylor and Francis. pp. 285–303.
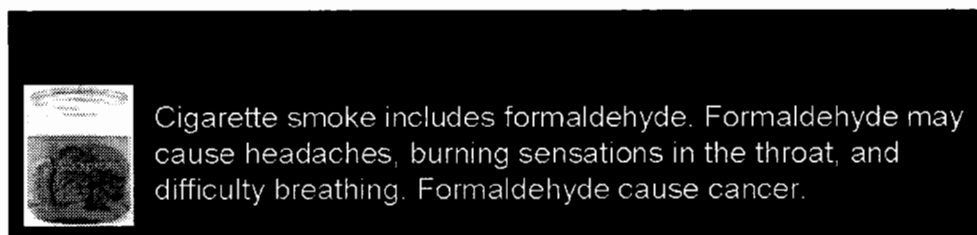
[5]Sojourner RJ, Wogalter MS. 1998. The influence of pictorials on the comprehension of and recall of pharmaceutical safety and warning information. Int J Cog Ergon 2:93–106.

[6]Kalsher MJ, Wogalter MS, Racicot BM. 1996. Pharmaceutical container labels and warnings: Preference and perceived readability of alternative designs and pictorials. Int J Indus Ergon 18:83–90.

[7] Leonard SD, Otani H, Wogalter MS. 1999. Comprehension and memory. In: Wogalter MS, DeJoy DM, Laughery KR, editors. Warnings and Risk Communication. London: Taylor and Francis. pp. 149–187.

- Widely recognized symbols, such as a skull, have been found to be especially effective in diverse populations, including among individuals with low literacy and education.[8]
- In a recent study, more children were able to recognize the skull symbol than any other hazard symbol.[9]

Second, different images could be used for each warning. Finding an image that smokers readily associate with a chemical may be easier in some cases than others. For example, formaldehyde is commonly used as an embalming fluid and lends itself well to an image (see example below). In contrast, chemicals such as benzene may have no recognizable associations or images.

Cigarette smoke includes formaldehyde. Formaldehyde may cause headaches, burning sensations in the throat, and difficulty breathing. Formaldehyde cause cancer.

Marker words

Marker words, such as "WARNING" may also be an effective addition to emission and constituent messages. Marker words for each warning should include at least one distinctive word to draw consumers' attention to the message. As with health warnings, marker words should have a larger font size and distinct font colour to attract attention.

[8]Banda SF, Sichilongo K. Analysis of the level of comprehension of chemical hazard labels: A case for Zambia. *Science of the Total Environment* 2006; 363: 22–27.
[9] Hara K, Mori M, Ishitake T, et al. Results of recognition tests on Japanese subjects of the labels presently used in Japan and the UN-GHS labels. *J Occup Health* 2007;49(4):260-7.

Step 2: Select Number of Messages and Rotation Period

To date, most countries require that only than one emission and constituent message appear on packages. In other words, the same descriptive information appears on all packages. This is a significant limitation of existing practices. Jurisdictions should design sets of between 4 and 8 different emission and constituent messages that would appear in rotation on packages. The rotation period for different sets of warnings should be the same rotation period as for the "main" health warnings on the face of packages.

Step 3: Existing Warnings

Before developing new emission and constituent warnings, existing warnings in other jurisdictions should be examined to help generate ideas. To date, the following countries have recently implemented descriptive emission and constituent warnings: Brazil, Uruguay, Venezuela, Chile, Australia, Thailand, and New Zealand.

◎ RESOURCE: Emission and Constituent Messages Online

An extensive list of emission and constituent warnings that have been implemented throughout the world can be reviewed at: www.tobaccolabels.org

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Step 4: Content of the messages

The general theme of emission and constituent messages is relatively fixed. However, there are a number of ways to communicate emission and constituent information, including the amount, type, and effects of chemicals.

Every attempt should be made to "personalize" the text of messages and to link chemical information to specific products and behaviour. As far as possible, the explanatory text should be linked directly with the act of inhaling or puffing to help

smokers visualize the process of ingesting chemicals. Recent focus group testing in Canada found that the following phrase was the most effective: "Every time you inhale, this product releases [chemical name] into your body." A second sentence describing specific health effects or providing specific health effects about the chemicals can follow. For example:

Sentence 1:
Every time you inhale, this product releases arsenic into your body.

Sentence 2:
Arsenic causes cancer of the lung, skin, bladder, liver, and kidney.

As with all health warnings, the text in emission and constituent messages should be as <u>clear</u> and <u>direct</u> as possible. Technical language should be avoided in all cases. For example, rather than saying that a chemical is "carcinogenic", messages should say that a chemical "causes cancer." Text should be at an appropriate literacy level.
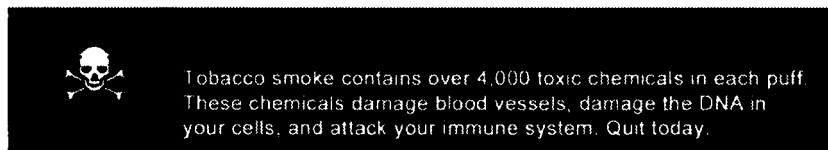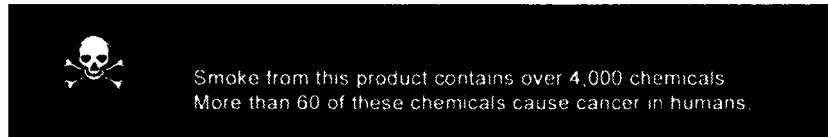
Amounts or levels of chemicals
As indicated previously, numbers that refer to the amount of chemicals for each brand (such as tar, nicotine, and carbon monoxide emissions) should <u>not</u> be displayed on packages. These numbers are derived from machine testing and are not related to the amount of chemicals released during human smoking.

Types of chemicals and health effects
There are two approaches to communicating the *types* of constituent and emission chemicals. The first is to include a general statement about the range of toxic or dangerous substances. For example, Australian messages mention "more than 40 harmful chemicals", while the Brazilian messages mention "4,700 toxic substances."

Focus group testing suggests that this may be an effective way to communicate the magnitude of toxic chemicals in tobacco smoke. These messages can be improved by adding a second sentence that refers to specific health effects.

Smoke from this product contains over 4,000 chemicals
More than 60 of these chemicals cause cancer in humans.

Tobacco smoke contains over 4,000 toxic chemicals in each puff.
These chemicals damage blood vessels, damage the DNA in
your cells, and attack your immune system. Quit today.

The second approach is to identify specific chemicals in consituents or emissions. Previous research commissioned by Health Canada found that the most common recommendation for improving the side messages was: "explaining the harmful effects of the chemicals found in cigarettes."[10] When shown a series of toxic emission messages, respondents were most likely to select the option that listed a specific chemical followed by an explanation of that chemical: "When shown a series of possible statements, smokers in a qualitative study were most supportive of texts that were short, clear, and simple and that presented only one substance with information on the impact that substance has on health.[11] See examples below.

Effects of chemicals

In addition to naming specific types of chemicals, the most effective emission and constituent messages also explain the effects of those chemicals. Several examples are provided below.

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[10] Toxics information on cigarette packaging: Results of a survey of smokers. Environics Research Group; May 2003.
[11] Summary Report of Four Focus Groups in Toronto & Montreal on Awareness and Understanding of Toxic Emissions Information on Tobacco Packaging; Environics Research Group Limited (2003b).

> ☠ Inhaling smoke from this product releases formaldehyde into your body. Formaldehyde causes cancer and can irritate the eyes, nose, and throat.

> ☠ Inhaling smoke from this product releases cadmium into your body. Chronic exposure to cadmium can lead to lung cancer and prostate cancer.

> ☠ Inhaling smoke from this product releases benzene into your body. Benzene causes leukemia and other cancers and is believed to be harmful at any level of exposure.

◎ *How should I choose what chemicals to display?*

As a first step, the most effective approach is to select chemicals that smokers already recognize as poisonous or toxic. In some countries, the general public is aware that chemicals such as arsenic and hydrogen cyanide are very dangerous, although few may be aware that they are present in tobacco smoke. Future versions or "rotations" of emission and constituent messages might also include chemicals that may be very dangerous, but for which there is little awareness. Descriptions of the effects of these chemicals will be particularly important.

Several countries have also developed toxic emission and constituent messages that focus on the nicotine, the primary addictive component of tobacco smoke. Messages on nicotine should go beyond the basic statement that tobacco smoke contains nicotine, a widely known fact in many countries. As far as possible, toxic emission messages should try to communicate new information or to make the addictive properties more vivid for consumers. An example is provided below.

> ☠ Tobacco smoke releases highly addictive chemicals into your body that reach your brain in seconds after inhaling. These chemicals are responsible for cigarette cravings and withdrawal symptoms.

> ⊚ *Should the messages explain the difference between tobacco constituents and smoke emissions?*
>
> No, the source of the chemical does not need to be explained to smokers. However some of the wording may need to be adapted depending upon whether it is referring to chemicals in the tobacco or the smoke. Messages for chemicals that are only found in constituents (i.e., the tobacco) should read: "This *product* contains..." or "This cigarette contains..." Messages for chemicals that are only present in emissions (i.e., chemicals only found in the smoke) should read: "Cigarette smoke contains..."

Step 5: Develop the Message

By Step 5, the layout and content of the messages should be established. At this point, the individual messages can be developed for testing.

Summary

As with health warnings, there is considerable value in pre-testing emission and constituent messages prior to implementation. This is particularly important given that less research has been conducted on these messages. It is highly recommended that resources be set aside for at least some pre-testing to ensure that the messages are not only noticeable and vivid, but also clear and easily understood. Pre-testing should also focus upon the effectiveness of using images and descriptions of specific health effects.

EVALUATING HEALTH WARNINGS & MESSAGES

BACKGROUND

The focus of this section is to describe how to pre-test and evaluate the impact of warnings. Although some jurisdictions have conducted extensive evaluation work before implementing health warnings, others have selected and implemented warnings with no pre-implementation evaluation. Although a lack of resources should never act as a barrier to implementation, even modest evaluation work is likely to increase the effectiveness of warnings.

The goal of this section is to describe a range of evaluation activities that can be adapted to local needs and the availability of resources. As with the previous section, special consideration has been made for jurisdictions with minimal resources for evaluation.

A. Pre-implementation: Pre-testing the layout and design of warnings

Primary Objectives

Jurisdictions that wish to explore new design features, or jurisdictions that require evidence of the impact of larger, pictorial warnings may wish to evaluate individual components of layout and design.

Priorities

The following layout and design features may be considered a priority for pre-testing:
- Text-only vs. picture warning
- Position of text vs. picture
- Inclusion of a government attribution
- Inclusion of a marker word
- Overall size of warning and relative size on the "front" and "back"
- Colour schemes, including contrast between background and text

Methods

The basic principle is to systematically evaluate each design feature so that strong conclusions can be drawn about their effectiveness. This involves creating different versions of the same warning that are identical, except for the feature that is being examined. In marketing research, this type of approach is often called "conjoint analysis." For example, if the value of pictures vs. text-only warnings were being evaluated, two warnings should be created that are identical, except for the addition of the picture. Therefore, the picture vs. text-only should be the same size, have the same text message, same border width, etc. An example is provided below.

Set A: Picture vs. text-only
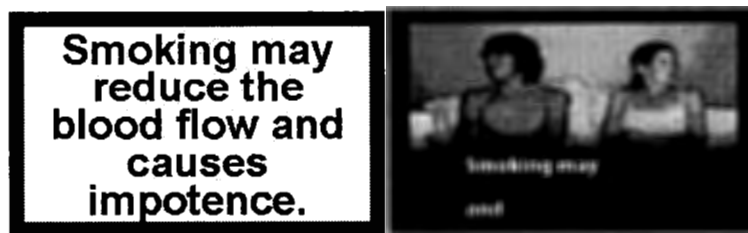
Set B: Picture vs. text-only

This approach ensures that if the warnings are rated differently by participants, the differences in scores can be attributed to the use of pictures—the only point of difference between the two warnings. Note that the picture that is selected to go along with the text will have some influence on whether the picture warnings are

rated as more effective. Therefore, it is important to repeat the process more than once, to ensure that the success or failure of the picture warnings is not simply due to a particular image. The best option is to use pairs of text-only and picture warnings across different themes. If the same pattern of results is found for both Sets A and B above, for example, the findings will be more robust.

Presentation of warnings and participant ratings
There are two approaches to presenting the warnings to participants. The first approach is to show both warnings in each "set" at the same time, and ask participants to directly compare the warnings. In the example above, participants would be shown both warnings from Set A and B, and asked which of the two warnings had greater immediate impact. The second approach is to show participants each warning one at a time and have participants rate the warnings separately. In other words, each warning would receive a score for immediate impact using a standard rating scale (see below), and these scores could then be compared to examine which warning was rated more highly. The advantage of the second approach—having participants rate each warning individually—is that warnings can then be compared across "sets" or themes fairly easily, without using statistical techniques. In other words, the impact ratings for each of the warnings in Set A could be compared with each of the warnings from Set B.

Developing the questions and rating scales
The design and layout of health warnings can be evaluated on a range of different "outcomes." Potential outcomes include the overall effectiveness of a warning, immediate "impact", noticeability, and the credibility of the information. The choice of outcomes should be guided by what is being evaluated. For example, if you are testing whether a government attribution should be included, you may be most interested in outcomes regarding the credibility of the warning.

Participants are often required to use a rating scale when responding to questions. Participants may be asked to rate each warning by selecting a number or symbol that corresponds to a particular category. The category is often written directly below the number or symbol, and typically ranges from "Very bad" to "Very good", or some version of these words. The use of a number or symbol along with the category helps to ensure that the rating scale is easily understood by low literacy smokers.

Examples of rating scales:

1	2	3	4	5
☆	☆☆	☆☆☆	☆☆☆☆	☆☆☆☆☆
☹☹	☹	☺	☺	☺☺
Very bad	**Bad**	**In the middle**	**Good**	**Very good**

Different questions should use the same rating scale for consistency. In other words, questions about immediate impact, noticeability, and credibility can all use the same 5-point rating scale. At the end of the process, each warning will have a set of ratings that can be compared across questions.

Note that in addition to questions specifically related to the health warnings, basic demographic variables should also be collected from participants, including smoking status, age, gender, and education level. Demographic variables can help to indicate whether different types of participants are providing different patterns of scores or ratings.

◉ *Should I use a focus group or survey when pre-testing warnings?*

Focus groups— A focus group is a form of qualitative research in which a group of people are asked about their attitude towards a product or concept. Questions are asked in an interactive group setting where participants are free to talk with other group members. Focus groups are an effective method for generating new ideas and concepts, particularly during the early stages of development. One limitation of focus groups is that the findings can be somewhat difficult to summarize given the unstructured nature of the group setting. In addition, the responses of each individual can be influenced by the group setting.

Brief Survey— In contrast to focus groups, surveys collect responses from each respondent individually, using more structured word and response options. The main advantage of conducting a survey is that responses can be collected more systematically for each individual, without social influences from other members in a group setting. One of the disadvantages to using surveys is that they are less effective than focus groups at exploring new ideas and concepts, although open-ended questions are capable of this to some extent. Surveys that are used to evaluate warnings will need to be conducted in-person or "face-to-face", rather than by telephone so that respondents can view images. "Self-completed" mail surveys and internet surveys are possible, although are less favourable in most cases.

A combined approach— The most effective and efficient approach may be a combination of surveys and focus groups. For example, participants can be recruited to a group setting, which may begin with a brief background survey on smoking status and demographics. The group can then be presented with the series of warning labels to be evaluated and instructed to complete written survey questions after each presentation. This should be done individually using structured questions, without group discussion or sharing of information. After all the warnings have been presented and the surveys have been completed, the

warnings can then be presented a second time with group discussion following each presentation. It is important to wait until all of the warnings have been presented and all survey questions have been completed before beginning any group discussion; otherwise opinions from different group members may affect how each individual responds to subsequent survey items. This "combined" approach yields structured responses at the individual level, as well as additional context from the group discussions that follow.

There are many other types of studies and techniques available to evaluate the layout and design of health warnings. Methods used to date include eye-tracking, fMRI, and other physiological responses which are all used to examine general levels of attention and the strength of first impressions. Each of these methods can be informative, but they are largely used for basic research purposes and are not necessary as part of a standard approach.

Target audience

A primary goal is to ensure that health warnings are easily understood among all smokers. To this end, it is absolutely critical that evaluation work includes participants with low levels of literacy and diverse socio-economic backgrounds. This is especially important given that, in most countries, smokers have lower levels of education than the general public. In order to ensure a suitable mix of participants, participants should be recruited from public areas with a cross-section of people, such as shopping areas and other public meeting places. In some cases, it may be necessary to specifically target and recruit participants from lower SES areas or occupations. Although many individuals are willing to participate in surveys, providing a small compensation in the form of a small gift or small amount of money can help to increase participation rates.

B. Pre-implementation: Concept and content testing

Primary Objectives

The main objective of concept and content testing are to evaluate the most effective health warning concepts for each theme and subject. Jurisdictions with both the time and resources often conduct this type of evaluation in several stages; initially to generate feedback on early concepts, as well as to test "final" versions before implementation.

Priorities

The main priorities are to ensure that each warning under consideration meets the following criteria:

- Strong initial impact.
- Consistency between text and picture.
- All text is clear and easily understood.
- Engaging and interesting text.
- Personal relevance and emotional impact.
- Credibility of message.
- Overall perceptions of effectiveness.

Methods

The basic principles are the same as evaluating layout and design: the process should be as systematic as possible, while also allowing for the possibility of broad feedback. Early testing of concepts and content is usually somewhat less structured. Often, very different concepts will be presented to participants to collect general feedback on which direction to pursue. However, as the content in the warnings becomes more defined, testing should become more systematic: the best way to test a specific concept is to develop similar versions of the same warning that differ only on one aspect of the content.
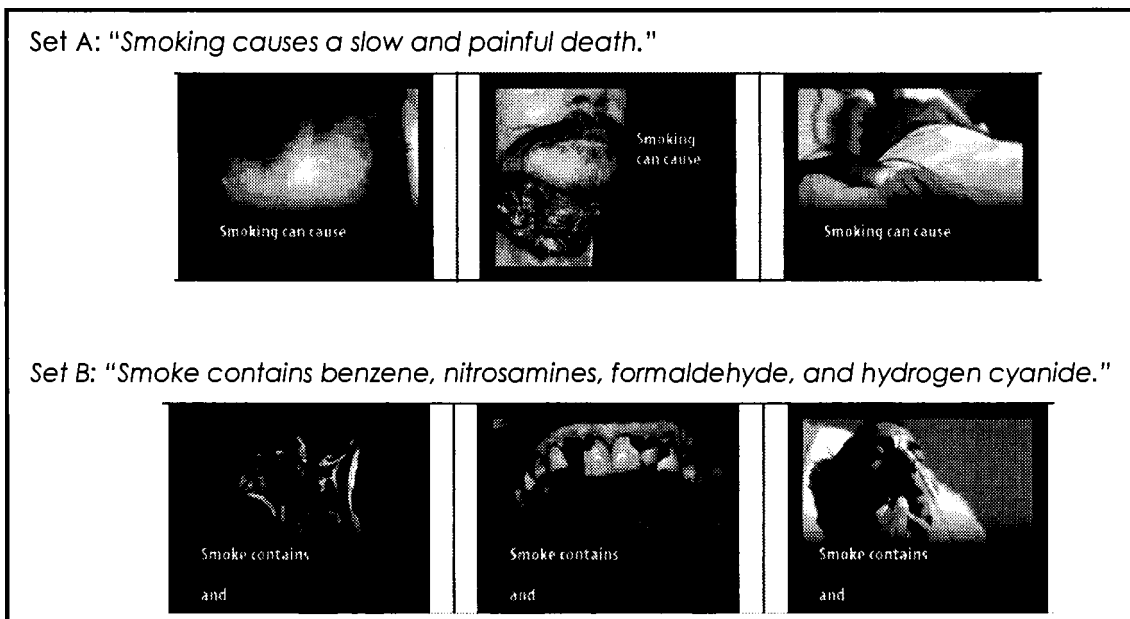
Developing the questions and rating scales

The main difference between layout/design and content/concept testing is the types of questions that will be asked. The questions should focus to a greater extent on how the information and content is received. Questions should be developed to measure immediate noticeability and impact, consistency between text and picture, clarity and meaning of text, interest in text, personal relevance, emotional impact, credibility of the information, and overall perception of effectiveness.

It is often helpful to ask about specific components of the warnings, such as the picture, text message, the cohesiveness of the pictures vs. text, etc. These types of questions provide important feedback about how to improve specific aspects of the warning. A typical approach would be to begin with a general question on the overall effectiveness of a warning before asking separate questions about each main component.

Presentation and Ratings

Several concepts should be developed for each theme or "message". See examples below, where three concepts were tested for each message.

Set A: *"Smoking causes a slow and painful death."*

Set B: *"Smoke contains benzene, nitrosamines, formaldehyde, and hydrogen cyanide."*

As with testing the design and layout, there are two approaches to presenting the warnings to participants. The first approach is to show each set of three warnings at the same time, and ask participants to indicate their preference. In the example above, participants would be shown all three warnings from Set A simultaneously and asked which of the three warnings had greater immediate impact, for example. The second approach is to show participants each warning one at a time and have participants rate the warnings separately. The advantage of the second approach is that it allows warnings from different sets to be compared without using statistical analyses. This is especially important to identify whether certain themes or subjects are performing poorly compared to others. In other words, it tells you not only which concept is the best execution of a particular theme, but which themes are having the greatest success.

Note that concept testing and evaluation of layout and design do not necessarily have to be completed in separate surveys or focus groups. In many cases, testing of layout and design is conducted prior to specific concept and content testing

only because basic decisions about text and pictures need to be determined before developing concepts. However, jurisdictions that wish to examine only a few novel layout or design features can incorporate elements of layout/design evaluation and concept/content evaluation in the same survey or focus group. Regardless, the process should be as systematic as possible with respect to the types of information that are varied and the types of questions that are asked.

Summary
Pre-testing of health warnings should be as rigorous as possible given available resources, but should not create any significant delays in implementation. It is possible to complete the entire process of development and pre-testing in several months if necessary, although you should allow at least 6-months for the process if possible. Longer periods will be helpful if time allows.

◎ CASE STUDY: Using the internet to engage and evaluate

In 2006, the Department of Health in the United Kingdom chose to develop a website as a way to engage the public on the issue of pictorial warnings and to solicit their feedback on different alternatives. Visitors to the website were asked to complete a number of demographic questions and to select the warnings they felt would be effective. Over 20,000 people completed the survey during the 3-months the website was in operation. The results were used to inform the final selection of images and received considerable media attention in the process.

C. Implementation evaluation: Monitoring & Compliance

Primary Objectives
The primary objective of monitoring compliance is to examine whether health warnings have been implemented on packages as planned. This type of

evaluation, often called "process" evaluation, is critical to measuring compliance to the regulations.

Priorities

The main priorities of this type of evaluation are to ensure that the warnings are appearing on packages as they were intended, as well as to ensure that the warnings begin appearing by the implementation deadline.

Methods

The most straightforward approach is to visit retail outlets to visually inspect packages. This type of approach is commonly referred to as an "environmental scan." Although there are formal protocols for conducting an environmental scan, even information approaches may be sufficient. The number of retail outlets visited will depend greatly on the availability of resources. While the number of retail outlets need not be exhaustive, a range of retail outlets in different parts of the country should be visited. In many cases, this requires relatively little expertise, with the potential to involve advocates and other public health officials if necessary. In addition, some regulators have visited factories of domestic tobacco manufacturers to ensure that packages are being printed in accordance with the regulations. Another approach is to encourage members of the public to report non-compliance, although this requires resources to publicize the phone number or reporting mechanism.

Overall, implementation evaluation for health warnings is considerably less resource-intensive than for other policies, such as smoke-free legislation. Efforts should focus on the immediate post-implementation period, after which relatively little monitoring is typically required.

D. Post Implementation: Impact Evaluation

Primary Objectives

The primary objective of impact evaluation is to examine the potential effectiveness of health warnings after implementation. In general, impact evaluations are not used to evaluate the effectiveness of individual warnings, but rather the impact of the health warnings as a whole.

Priorities

One of the main priorities is to measure potential "wear-out" of the warnings and the point at which new warnings may be required. This requires measuring whether the health warnings have met and continue to meet their objectives. Although the objectives of health warning systems may differ to some extent across jurisdictions, common objectives include the following:

- Increases in health knowledge and perception of risk.
- Greater awareness of cessation services.
- Increases in motivation to quit and cessation.

Methods

Population-based surveys provide the most comprehensive method for evaluating the impact of health warnings. Ideally, surveys should be conducted <u>before</u> and <u>after</u> the implementation of new warnings. These surveys should also use similar questions and methodology so that changes in key outcomes can be examined. Whereas some jurisdictions have conducted entire surveys devoted to evaluating the impact of health warnings, it is also possible to insert a smaller number of questions into on-going surveys that include other topics. Basic principles for survey design and analysis are provided in the IDRC "Focus Group" resource, presented earlier in this section, as well as the resource described below.

> **◎ RESOURCE: Designing impact evaluation surveys**
>
> A detailed discussion of questions used to evaluate the impact of health warnings
> is included in a Monograph from the International Agency for Research on
> Cancer. The Monograph Chapter can be requested from:
> dhammond@uwaterloo.ca

Questions

The first step in developing questions to evaluate warnings is to identify potential outcomes of interest. Common outcomes include the following:

- Are the health warnings being noticed and how do they compare with other forms of health information?
- To what extent do smokers "process" the warnings in terms of thinking about and discussing warnings?
- Do smokers believe the information in the warnings is credible?
- Have the warnings increased levels of health knowledge and perceived risk?
- Are smokers more likely to quit due to the health warnings?
- Do health warnings reduce the appeal of the package?
- What is the level of public support for health warnings?

The resource listed above includes examples and a discussion of these and other survey questions.

> ⊚ **"Can I use prevalence figures to evaluate the impact of warnings?"**
>
> Prevalence rates from large national surveys provide the estimate of population-wide changes in smoking behaviour. However, there are several limitations to using prevalence data as a measure of whether health warnings have been effective in promoting cessation. The Canadian experience provides a good illustration of these limitations. In the six years since 2001, when large pictorial warnings were implemented in Canada, the prevalence of smoking has decreased by approximately 4%. This represents a substantial decrease of approximately one million smokers in six years—a considerable public health achievement. However, it would be inaccurate to suggest that the health warnings were responsible for all or even most of the 4% decrease in smoking. Indeed, over this six year period the price of cigarettes have increased, several mass media campaigns have been conducted, and smoke-free legislation has become considerably stronger in Canada. In other words, prevalence data are not specific to health warnings or any other single intervention. Therefore, while health warnings may have played an important role in reducing smoking in Canada, there is no way to precisely estimate the contribution.
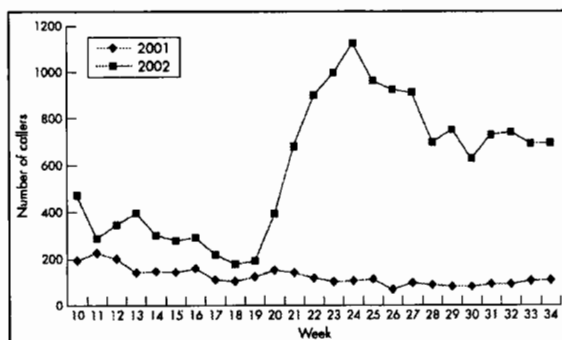
Other considerations

Timing of surveys

Several months often pass between the implementation date of new health warnings and the time at which they begin appearing on most packages. In addition, the cumulative impact of health warnings may build over time, with repeated exposures to the different messages. As a result, surveys that seek to measure the impact of warnings should wait at least 6 months after the implementation date. Ideally, regular surveys would be conducted to examine potential wear-out of the warnings in the long term, perhaps at 12 or 24-month intervals, if necessary.

Target groups

Unlike some other aspects of evaluation, impact evaluations should include both smokers and non-smokers. The extent to which non-smokers notice and recall health warnings is a very good indication of their overall effectiveness in the general population.

⊚ CASE STUDY: Using different sources of data to evaluate health warnings

Concerns about health risks of smoking are among the most common and important reasons for quitting smoking; however, there are a number of other factors that also contribute to the decision to quit and whether or not a quit attempt is successful. Although it may be impossible to measure the precise number of smokers who quit as a direct result of health warnings, some jurisdictions have used alternative data sources to estimate the potential impact, such as tracking the use of cessation services. For example, the UK, the Netherlands, Brazil, and Australia have tracked calls to the free telephone "quitline" number that is displayed on packages in each country. In each case, calls to the national quitline have increased significantly immediately after the telephone number appears on packages. For example, the graph below shows the increase in calls to the Netherlands quitline service after the number was printed on the back of one of 14 package warnings, beginning in Week 19 of 2002. This type of data source indicates that, at the very least, the health warnings are helping to increase the use of effective cessation services.

Source: Willemsen M., Simons C, Zeeman g. Tobacco Control 2002;11: 381-2.

IMPLEMENTATION

5.0 IMPLEMENTATION

This section review several considerations leading up to the implementation stage of new labelling policies.

Public consultation

Parties should inform the public about proposals to introduce new labelling regulations. One option is to release information through a consultation paper, which can be publicized through the media. Community involvement can also be promoted by holding community workshops. Consultation papers and workshop provide an opportunity to communicate the rationale behind labelling proposals, to share the supporting evidence, as well as to help refined concepts. These activities not only provide helpful feedback on proposals, but also help to generate public support prior to implementation. These activities can be conducted in parallel with the development of new designs and preparation of the regulatory process to prevent unnecessary delays.

Communications and media strategy

The implementation of comprehensive health warnings and other labelling measures tend to be high profile events and Parties should expect considerable media interest. Those responsible for responding to media requests should be prepared to communicate the basic rationale for the regulations, as well as to respond to common complaints and arguments (see below). Timely information should be provided to the media as media coverage can increase the educational impact of new messages. Partners in civil society and non-governmental organizations can also play an important role in publicizing new regulations.

Linking with other tobacco control activities

The introduction of new health warnings and messages represents an excellent opportunity to link and leverage other policy initiatives. Where resources allow, mass media initiatives timed to coincide with the new messages appearing on the market. A coordinated media campaign will reinforce warnings and messages, improve access to target groups, provide additional information on health warnings and messages and also communicate other information that increases tobacco users motivation and confidence in their ability to quit, such as the benefits of quitting, attitudes to quitting, quit advice and contact details of quit organizations.


◎ CASE STUDY: Linking health warnings with other media campaigns

One consideration when developing the warnings is to link them with other mass media or education campaigns in your country. The Australian experience provides a very good illustration of this. One of the pictorial health warnings implemented in 2007 included a theme and subject that was featured in a very successful and well known television campaign that depicted the effects of smoking on arteries. Incorporating the same theme and subject in the package warnings provided an opportunity to capitalize upon this successful campaign and to provide constant reminders to smokers.
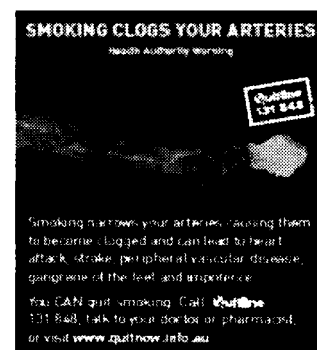
New South Wales, one of the five Australian states, also used the health warning messages as a basis for advertisements on the side of busses (see right), as well as several television spots. In both the bus and television spots, the advertisements helped to make the information in health warnings more vivid and provided a compelling narrative to the pictures and text. Smokers who see these advertisements are likely to recall them each time they see the related images on the pack. The print and television ads can be viewed at: http://www.cancerinstitute.org.au/cancer_inst/ca mpaigns/healthwarnings2006.html
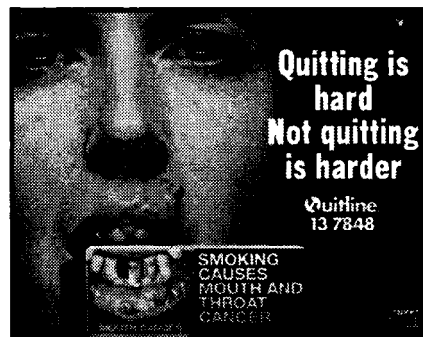
Dealing with industry opposition & barriers

The tobacco industry has generally opposed the introduction of large pictorial health warnings on packages. [12] For example, as Alechnowicz and Chapman[13] have noted, in 1995, package warnings were identified by British American Tobacco one of the key issues facing the company. Protecting the pack design and "neutralizing" the controversy over pack warning labels were among the priorities listed in the document.[14] The same document goes on to state that, "pictorial warnings, and those occupying a major pack face or faces (front and back) or a disproportionately large area of

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[12] Chapman S, Carter SM. "Avoid health warnings on all tobacco products for just as long as we can": a history of Australian tobacco industry efforts to avoid, delay and dilute health warnings on cigarettes. *Tob Control* 2003; 12 Suppl 3:iii13-22.

[13] Alechnowicz K, Chapman S. The Philippine tobacco industry: "the strongest tobacco lobby in Asia". *Tob Control* 2004;13 Suppl 2:ii71-8.

[14] BAT (British-American Tobacco Company). 1995. *1995 Key Area Paper: Corporate Affairs*. Web Page. Available at: http://www.library.ucsf.edu/tobacco/batco/html/7200/7265/otherpages/allpages.html

advertising space, should be restricted, as should moves to plain or generic packs. Every effort should be made to protect the integrity of the company's packs and trade marks".[143]

Although tobacco manufacturers have launched legal challenges in countries such as Canada and the European Union, health warning legislation was upheld by the courts in both cases. Although legal challenges are relatively rare, Parties should be prepared to counter common grounds of opposition. The section below summarizes common industry arguments.

Printing capacity & technology
Tobacco manufacturers have previously argued that they lack the technology to print colour pictorial warnings or that the costs of altering their existing printing methods would be prohibitive. Although manufacturers must bear the costs of redesigning their printing practices, such as the costs of re-etching press cylinders or preparing new lithographic printing plates, the technology required to print colour warnings is widespread. In every case to date, the printing changes required by manufacturers can be addressed by providing sufficient notice to manufacturers between the announcement of new regulations and the implementation deadline.

Violation of rights & trademarks
Tobacco manufacturers have argued that large health warnings represent unjustified violations of their rights to freedom of expression and their trademarks. However, courts in Canada have ruled that large warnings were justified given the serious health risks from these consumer products and the consequences for public health.

Infringement of Trade Agreements
Manufacturers in the European Union argued that the labelling directive infringed on Article 20 of the Agreement on the Trade-related Aspects of Intellectual Property

Rights ('the TRIPs Agreement') as set out in Annex 1 C of the WTO Agreement. The European Court of Justice dismissed this argument and upheld the law.

Excessive and Unnecessary

One of the most common arguments against comprehensive warnings is that they are "excessive" and unnecessary, given that most smokers are already aware that smoking is harmful. In fact, virtually all smokers—including those in the most affluent and highly educated societies—fail to understand the full range, likelihood, and severity of health effects from smoking. There is also ample evidence, presented in Chapter 1, that larger, more comprehensive warnings are more effective in communicating this health information—especially among children and others unable to read text warnings. In addition, as the following quote from the Quebec Court of Appeal indicates, the health warnings also help to provide a constant reminder of the health risks.

> *"...even if all smokers and potential smokers were very well aware of the risks associated with tobacco use, Parliament would still be justified in insisting that they be reminded once again of the harmful health consequences of smoking each time they take a cigarette from their packs."*[15]

Harassing smokers

Tobacco manufacturers commonly portray more comprehensive health warnings as an example of the government attacking or harassing smokers. For example, in 2004, former Chairman of BAT, Martin Broughton, argued:

> *"Some health policymakers show signs of having been `captured' by narrowly based, vociferous anti-tobacco activists, who are sometimes even funded by the regulators they are lobbying," said Mr Broughton, who is leaving to chair British Airways later this year. "An example is the growing use of `graphic image' health warnings, which threaten our intellectual property rights and can harass consumers - yet in fact give them no more information than print warnings."*[16]

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[15] JTI-Macdonald Corp., Rothmans, Benson & Hedges Inc and Imperial Tobacco Canada Ltd. v. Attorney General of Canada (Quebec Court of Appeal). 2005. [196]

[16] Stevenson R. BAT chief bows out in fit of anger. The Independent; London. 22 April 2004.

In fact, there is evidence from a number of countries that large pictorial warnings are not only supported by a strong majority of non-smokers, but also by most smokers. Indeed, many smokers welcome more health information on their packages, particularly when it includes support for quitting. In addition, support for large pictorial warnings typically increases over time. Therefore, industry claims that comprehensive warnings represent government attacks on smokers are not shared by most smokers themselves.

LEGISLATION

6.0 LEGISLATION

This chapter provides recommendations for drafting labelling regulations, particularly with respect to health warnings. Packaging and labelling legislation should be as specific as possible to minimize the possibility of loopholes. A lack of specificity may be exploited by tobacco companies and thus reduce the intended benefits of the regulations. Note that this section does not cover all aspects of labelling regulations; rather it is only meant to provide guidance on key issues.[17]

Source document
The most effective approach for health warnings and messages is to include a "source document" in the legislation. A "source document" is a stand alone document referred to in regulations (or included in the regulations, such as in a Schedule or Annex) that visually depicts in full colour the warning messages (including both text and image components) as they are to appear on packages. Using a source document removes the need to specify details such as the font style, given that they are already incorporated in the messages themselves. A number of jurisdictions, including Canada and the European Community have used this approach—examples of these source documents are available for download at: www.tobaccolabels.org. A source document may be in electronic form, such as on a CD.

Specific considerations

Rotation of messages
The rotation period for "sets" of warnings (e.g. every 24-months) should be clearly specified in national legislation. Legislation should also specify that each health warning message appear in equal proportion for each stock keeping unit (each

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[17] Several sections in this chapter have been drawn from a Framework Conventional Alliance briefing paper prepared for the Article 11 Working Group: http://www.fctc.org/index.php

format/size of each brand variation). Thus all warnings should appear in equal rotation for Marlboro 100mm 20 pack, for Marlboro 100mm 25 pack, for Marlboro 100mm Menthol 20 pack, etc.

Printing and Quality of Messages
Parties should consider specifying minimum printing requirements. For example in the European Community Directive, picture warnings are to "be printed in four-colour/-CMYK-/ screen 133 lines per inch, as a minimum requirement." The UK and Belgium, for instance, have implemented this required standard.

Legislation should also indicate that health warnings should be parallel to the top edge of the package surface to prevent manufacturers printing warnings at an angle or upside down.

Different shaped packages & cartons
For soft packs, depending on the design of the package and of the warning, the top edge of the warning should be required to be lowered sufficiently on the package surface so that the warning is not severed when the package is opened in the normal way. When some soft packs are opened, the top of the package is permanently removed, and a small portion of the front and back of the package may be removed as well (although for other soft packs, the foil folds open and shut at the top). If a substantive part of the health warning was removed, this would be of concern. If there was a border surrounding the warning (e.g. 3-4mm black border), and only part of the border was removed, this would be of less concern. Other considerations for package sizes include:

• Cylindrical containers (such as for roll-your-own tobacco): Canada has requirements to ensure that the warning appears twice on cylindrical containers, effectively on what could be considered the "front" and "back"; Singapore also has specific requirements; Australia and New Zealand have specific requirements for cylindrical and elliptical containers;

- Bundles of cigars with no packaging: Canadian regulations specify that a label is to be placed on the bundle;

- Individually packaged cigars: warnings should be required to be placed horizontally to ensure better visibility;

- Leaf tobacco sold for consumer use (sometimes sold without packaging, and sometimes referred to as a "hand" of tobacco): a warning on a cardboard or other tag of a specified size could be attached with an elastic, string or other device (somewhat akin to a luggage tag affixed to a suitcase, or a price label for a lamp or some other products).

- Cartons: health warnings should also be located on all sides of <u>cartons</u>. Depending on carton format/dimensions, Parties should consider requiring that a picture-based warning be repeated and appear several times, instead of just appearing once.

Obscuring Messages

Parties should prohibit the industry from obscuring a mandatory package message, such as by printing anything or affixing anything (e.g. a sticker) on the package or on the cellophane in a way that blocks a mandatory message.

Exemptions

No exemptions should be allowed to these requirements. For example, there should not be exemptions for small volume companies or brands. Nor should there be exemptions for products sold in duty-free stores.

Tax markings

When determining packaging and labelling requirements under Article 11, Parties should recall obligations related to packaging under Article 15.2 of the FCTC (illicit trade), including:

- that the origin of the product must be indicated on the package and any outside packaging, e.g. "Made in country X" (Article 15.2);
- "that unit packets and packages of tobacco products for retail and wholesale use that are sold on its domestic market carry the statement: "Sales only allowed in (insert name of the country, subnational, regional or federal unit)" or carry any other effective marking indicating the final destination or which would assist authorities in determining whether the product is legally for sale on the domestic market" (Article 15.2(a)).

Parties should avoid a situation where tax-related markings/stamps cover or replace the area devoted to warnings or other mandatory labelling information.

Implementation period

When implementing new or modified packaging and labelling requirements, one option is for Parties to ensure that there are two implementation dates: one date for manufacturers/importers, and a later date for wholesalers/retailers. Another option would be to have one implementation date that would apply to all levels, including manufacturers/importers, wholesalers, and retailers. At the manufacturer/importer level, the transition period should not be longer than one year from the date the regulation is finalized, although a shorter transition period, such as six months, is preferable. For manufacturers, there should be a ban on not only manufacturing/packaging products with old packages after the implementation date, but also a ban on distributing as well. This would prevent manufacturers from stockpiling product with old packaging.

If a wholesaler/retailer has non-compliant product past the implementation date, that product should be able to be seized by enforcement officials. It is important to have a final implementation date at the wholesaler/retailer level in addition to the manufacturer/importer level. For example, when Australia and Canada

implemented picture-based warnings, there was no implementation date at the retailer level.

Pre-emption

Parties should ensure that packaging and labelling requirements do not relieve tobacco manufacturers and/or others from any obligations to consumers and others, such as to provide further health warnings other than those required by legislation. For example, Parties should avoid including in legislation a pre-emption provision indicating that manufacturers are not liable for an absence of warning messages beyond the messages required by legislation, or that sub-national levels of government may not have additional packaging and labelling requirements.

◉ RESOURCE: Library of existing regulations

Copies of labelling regulations from dozens of countries is available at:

www.tobaccolabels.org

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